

Exhibit I

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC)
REPAIR SYSTEM PRODUCTS)
LIABILITY LITIGATION)
_____)
THIS DOCUMENT RELATES TO THE)Master File No.
FOLLOWING CASES IN WAVE 1 OF)2:12-MD-02327
MDL 200:) MDL 2327
Marty Babcock v. Ethicon, Inc.)JOSEPH R. GOODWIN
Civil Action No. 2:12-cv-01052)U.S. DISTRICT
JUDGE
[Complete caption below])

DEPOSITION OF
SCOTT GUELCHER
Taken on behalf of the Defendants
March 23, 2016
8:51 a.m.

GOLKOW TECHNOLOGIES, INC.
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13 Civil Action No. 2:12-cv-01052)U.S. DISTRICT
14)JUDGE
15 Daphne Barker, et al. v.)
16 Ethicon, Inc., et al.)
17 Civil Action No. 2:12-cv-00899)
18)
19 Dorothy Baugher v. Ethicon,)
20 Inc., et al.)
21 Civil Action No. 2:12-cv-01053)
22)
23 Harriet Beach v. Ethicon,)
24 Inc., et al.)
Civil Action No. 2:12-cv-00476)
Myra Byrd, et al. v. Ethicon,)
Inc., et al.)
Civil Action No. 2:12-cv-00748)
Fran Denise Collins v.)
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Civil Action No. 2:12-cv-00931)
Dennis W. Dixon, Estate of)
Virginia M. Dixon,)
Deceased v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01081)
Lois Durham, et al. v.)
Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00760)
Karen Forester, et al. v.)
Ethicon, Inc., et al.)

1	Shirley Freeman, et al. v.)
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2	Civil Action No. 2:12-cv-00490)
)
3	Monica Freitas, et al. v.)
	Ethicon, Inc., et al.)
4	Civil Action No. 2:12-cv-01146)
)
5	Susan Guinn v. Ethicon, Inc.,)
	et al.)
6	Civil Action No. 2:12-cv-01121)
)
7	Wendy Hagans v. Ethicon, Inc.,)
	et al.)
8	Civil Action No. 2:12-cv-00783)
)
9	Beth Harter, et al. v. Ethicon,)
	Inc., et al.)
10	Civil Action No. 2:12-cv-00737)
)
11	Rocio Herrera-Nevarez v.)
	Ethicon, Inc., et al.)
12	Civil Action No. 2:12-cv-01294)
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13	Mary Holzerland, et al. v.)
	Ethicon, Inc., et al.)
14	Civil Action No. 2:12-cv-00875)
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15	Lois Hoy, et al. v. Ethicon,)
	Inc., et al.)
16	Civil Action. 2:12-cv-00876)
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17	Myndal Johnson v. Ethicon,)
	Inc., et al.)
18	Civil Action No. 2:12-cv-00498)
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19	Holly Jones, et al. v. Ethicon,)
	Inc., et al.)
20	Civil Action No. 2:12-cv-00443)
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21	Debra Lynn Joplin v. Ethicon,)
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4	Civil Action No. 2:12-cv-00755)
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5	Heather Long v. Ethicon, Inc.,)
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6	Civil Action No. 2:12-cv-01275)
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7	Donna Massey, et al. v.)
	Ethicon, Inc., et al.)
8	Civil Action No. 2:12-CV-00880)
)
9	Angela Morrison, et al. v.)
	Ethicon, Inc., et al.)
10	Civil Action No. 2:12-cv-00800)
)
11	Maria Eugenia Quijano v.)
	Ethicon, Inc., et al.)
12	Civil Action No. 2:12-cv-00799)
)
13	Penny Rhynehart v. Ethicon,)
	Inc., et al.)
14	Civil Action No. 2;12-cv-01119)
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15	Victoria Rock v. Ethicon,)
	Inc., et al.)
16	Civil Action No. 2:12-cv-00867)
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17	Denise Sacchetti v. Ethicon,)
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18	Civil Action No. 2:12-cv-01148)
)
19	Debra A. Schnering, et al. v.)
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20	Civil Action No. 2:12-cv-01071)
)
21	Sheri Scholl, et al. v.)
	Ethicon, Inc.)
22	Civil Action No. 2:12-cv-00738)
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24	Civil Action No. 2;12-cv-00967)

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3 Cherise Springer, et al. v.)
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4 Civil Action No. 2:12-cv-00997)
)
5 Margaret Stubblefield v.)
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6 Civil Action No. 2:12-cv-00842)
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7 Lisa Thompson, et al. v.)
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8 Civil Action No. 2:12-cv-01199)
)
9 Mary Thurston, et al. v.)
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10 Civil Action No. 2:12-cv-00505)
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11 Shirley Walker, et al. v.)
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12 Civil Action No. 2:12-cv-00873)
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13 Cathy Warlick v. Ethicon,)
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14 Civil Action No. 2:12-cv-00276)
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15 Laura Waynick, et al. v.)
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16 Civil Action No. 2:12-cv-01151)
)
17 Rebecca Wheeler, et al. v.)
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18 Civil Action No. 2:12-cv-01088)
)
19 Nancy Williams v. Ethicon,)
Inc., et al.)
20 Civil Action No. 2:12-cv-00511)
)
21 Thelma Wright v. Ethicon,)
Inc., et al.)
22 Civil Action No. 2:12-cv-01090)
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QUESTIONS INSTRUCTED NOT TO ANSWER

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I understand that. But I'm -- my question 96
is related to these 44 women. Can you tell
us, to a reasonable degree of scientific
certainty, whether or not the mesh, in any
of these 44 women, ever oxidized?

I'm asking, Doctor, can it ever 162
be completely -- can oxidation ever be
completely eliminated?

1 SCOTT GUELCHER

2 was called as a witness, and after having been
3 first duly sworn, testified as follows:

4

5 (Whereupon Exhibit 1 was marked as an
6 exhibit.)

7

8 EXAMINATION BY MR. HUTCHINSON:

9 Q. Good morning, Dr. Guelcher. Chad
10 Hutchinson, counselor for Ethicon.

11 I'll hand you what we've marked as
12 Exhibit 1 to your deposition. Have you seen that
13 deposition notice before?

14 A. Yes.

15 Q. And did you bring any documents with
16 you responsive to that deposition notice?

17 A. I did not.

18 MR. HUTCHINSON: Counsel, I understand
19 you're producing a flash drive right now, more or
20 less as we speak, that will contain what?

21 MR. BOWMAN: It will contain everything
22 he reviewed, and it is on his reliance list.

23 MR. HUTCHINSON: And it will not
24 contain any new testing; is that correct?

1 MR. BOWMAN: There -- the testing
2 that's been done has been produced in the past.
3 There's nothing new produced today.

4 BY MR. HUTCHINSON:

5 Q. Dr. Guelcher, what are the names of the
6 products that you're -- you're here to give
7 testimony about?

8 A. I believe the SUI slings and the POP
9 devices that would include the GYNEMESH, the TVT,
10 TVT-O, is my understanding. I have to look at my
11 report for all the list of the names.

12 Q. Sure. And I'll hand you what we'll
13 mark as Exhibit 2 to your deposition.

14 A. Okay.

15 (Whereupon Exhibit 2 was marked as an
16 exhibit.)

17 THE WITNESS: That would help me.

18 MR. HUTCHINSON: Sure. Counsel.

19 MR. BOWMAN: Thank you.

20 THE WITNESS: Did you -- is there still
21 a question?

22 BY MR. HUTCHINSON:

23 Q. Yes, sir.

24 A. Oh.

1 Q. I'm waiting for your answer.

2 A. Oh.

3 Well, as I stated in my report, these
4 are the SUI, stress urinary incontinence, and the
5 pelvic organ prolapse, POP, devices. This would
6 include PROSIMA, PROLIFT, GYNEMESH, the TVT
7 devices. All of these devices are made from
8 PROLENE.

9 Q. All right. Which specific SUI slings
10 are you here to give testimony about?

11 A. There's 200 cases in this wave. My
12 understanding is some of these are TVT, TVT-O.
13 Those are the ones I can remember right now.

14 My report was directed more toward the
15 polypropylene, PROLENE, polypropylene that's used
16 to make those devices.

17 Q. TVT and TVT-O are the only two names of
18 the products that you can remember for SUI devices?

19 A. There's a -- I'm sorry. There's a
20 TVT-S. Those are the ones that I can remember
21 right now.

22 Q. Okay. Can you remember any others?

23 A. I think that's what I can remember
24 right now.

1 Q. What does TVT-S stand for?

2 A. That's the -- the shorter sling, so
3 the -- the -- the TVT is a longer sling. The TVT-S
4 is shorter.

5 Q. Okay. And what does TVT-S stand for?

6 A. I -- I don't remember the meaning
7 behind the acronym right now. The TVT is a
8 transvaginal tape, but I don't -- I don't -- I
9 don't remember exactly what the S stands for right
10 now.

11 Q. Which -- which POP or pelvic organ
12 prolapse devices are you here to give testimony
13 about? Which specific ones?

14 A. Well, they're listed in the report, the
15 PROSIMA, the PROLIFT, and the GYNEMESH.

16 Q. Any others?

17 A. Those are the ones I can think of right
18 now.

19 Q. What about PROLIFT+M? Are you here to
20 give testimony today about PROLIFT+M?

21 A. Yes. The PROLIFT+M is also mentioned
22 in the report. That -- well -- okay. It's -- it's
23 a hybrid material that has the -- the MONOCRYL
24 polyester resin with the PROLENE. So that's in the

1 report as well.

2 Q. And, Doctor, you're referring to
3 Exhibit 2, which is your expert report; is that
4 correct?

5 A. I am.

6 Q. Is this report complete and accurate?

7 A. Yes.

8 Q. Is this a final version?

9 A. Yes. I -- I -- I believe so.

10 Q. How many hours did you spend on this
11 report?

12 A. I -- I don't know. I don't -- I don't
13 track the hours. I don't -- I don't know how many
14 hours I spent.

15 Q. Okay. How do you bill the attorneys
16 for your time?

17 A. So that was a -- a billing sheet that I
18 believe I produced with the report, where we just
19 bill by the report. And this was, I believe, a --
20 what I would call a medium report.

21 Q. What is a medium report?

22 A. It's -- in the billing, I just break it
23 down and do a short report, a medium, and a long
24 report. This one would have been in the medium

1 category.

2 Q. So would that be a flat fee for this
3 report?

4 A. That's correct.

5 Q. What is the flat fee for this report
6 that --

7 A. It's \$10,000. Yeah.

8 Q. Marked as Exhibit 2?

9 A. That's correct.

10 Q. And are all -- are all of the opinions
11 that you intend to offer in this litigation
12 contained in your expert report marked as Exhibit
13 2?

14 A. Yes, they are.

15 Q. I've handed you, also, a CV, which is
16 part of Exhibit 2.

17 A. Yes.

18 Q. Is that the most recent version of your
19 CV?

20 A. I believe so. I have to check it
21 briefly. But I believe this is the -- this is the
22 current version. Okay. Yes.

23 Q. And your reliance list is also marked
24 as Exhibit 2. Is that the most current reliance

1 list?

2 A. I believe so. Again, I'd like to check
3 it for just a second. I believe so.

4 Q. Okay. Doctor, other than attorneys,
5 have you discussed your opinions, as they relate to
6 pelvic organ -- pelvic organ prolapse products,
7 with anyone else?

8 A. With -- Dr. Dunn and I have been
9 working together on this litigation with the
10 attorneys.

11 Q. And other than Dr. Dunn, have you
12 discussed your opinions regarding pelvic organ
13 prolapse products with anyone else?

14 A. No. I'm sorry. Dr. Iakovlev.

15 (Reporter interruption for
16 clarification.)

17 THE WITNESS: I'm sorry. Dr. Iakovlev,
18 I-a-k-o-v-l- -- do you mean -- can I clarify? Do
19 you mean in this specific report the opinions --
20 like this --

21 BY MR. HUTCHINSON:

22 Q. (Indicating yes.)

23 A. Are you talking about this specific
24 report or -- yeah. I've not discussed this report

1 with Dr. Iakovlev. I -- I wrote the paper with
2 him, but. . . I guess I'm a little confused about
3 the question.

4 Q. Okay. So the question is I want you to
5 talk about your opinions as they relate to pelvic
6 organ prolapse products.

7 A. Yes.

8 Q. Have you discussed those opinions with
9 anybody other than Dr. Dunn and Dr. Iakovlev?

10 A. Not other than attorneys, I can't
11 think. . .

12 Q. Never spoken to any other scientist or
13 medical doctor about those opinions; is that
14 correct?

15 A. So I -- I have presented at -- at
16 meetings, the IUGA meeting last year in Nice.

17 Q. And we're going to get to that --

18 A. Okay.

19 Q. -- but I want to talk about your
20 opinions as they relate to pelvic organ prolapse
21 products.

22 A. Okay.

23 Q. Have you discussed those with any
24 scientist or medical doctor?

1 A. At the meeting there was some
2 discussion among the meeting participants. But --

3 Q. Was this -- excuse me.

4 A. Sorry. Go ahead. Yeah.

5 Q. Was this that meeting in France?

6 A. Yeah. That's right.

7 Q. Other than in France, have you ever
8 discussed any of those opinions with anyone else?

9 A. I've presented it at a meeting at -- at
10 the American Institute of Chemical Engineers in the
11 fall of 2014. Presented a talk there.

12 Q. Your opinions as they relate to pelvic
13 organ prolapse products?

14 A. I don't -- you know, I don't know that
15 we had the POPs in that talk. I think that was
16 slings.

17 Q. Okay.

18 A. So we talked about polypropylene
19 oxidation.

20 Q. I understand that.

21 A. Not necessarily about the POP devices.

22 Q. Okay.

23 A. I'm just trying to understand what
24 you're asking.

1 Q. Fair enough. My question, though, as
2 it relates to pelvic organ prolapse products, have
3 you discussed those opinions as they relate to
4 pelvic organ prolapse products with anyone else?

5 A. I -- I don't believe so.

6 Q. Doctor, have you -- have you ever told
7 any doctor at Vanderbilt that you have concerns
8 about the safety of polypropylene or PROLENE mesh?

9 A. I had some email correspondence with a
10 Vanderbilt OB/GYN. I had some -- we -- it wasn't
11 about -- it wasn't about opinions about the
12 products. It was about research on polypropylene
13 oxidation. But I haven't discussed my opinions
14 with them.

15 Q. Okay. Do you know how many doctors
16 practice medicine at Vanderbilt?

17 A. No.

18 Q. Have you ever told a doctor at
19 Vanderbilt that you believe PROLENE mesh degrades
20 via oxidation?

21 A. No. I haven't had the opportunity.

22 Q. Doctor, you -- your lawyers -- or a
23 lawyer sitting to the right of you is producing me
24 a flash drive with all the documents you have

1 reviewed; is that correct?

2 A. That's right.

3 Q. And would those be internal Ethicon
4 documents, at least some of them?

5 A. Some of them are. Yeah.

6 Q. Have you ever signed a confidentiality
7 agreement with respect to the documents that you've
8 reviewed from Ethicon?

9 A. I can't remember. Probably. I don't
10 remember.

11 Q. Where would it be if you did?

12 A. I don't know. I don't know that I have
13 that agreement.

14 Q. Where would you look for it if you had
15 it?

16 A. Well, I would think the attorneys would
17 have it. I -- I don't -- I just don't know that
18 I've ever signed it.

19 Q. Do you remember being deposed in the
20 Mullins litigation?

21 A. Mullins?

22 Q. Mullins. It's the -- was -- it was 37
23 consolidated --

24 A. It was consolidated in West Virginia?

1 Q. (Indicating yes.)

2 A. Okay.

3 Q. Do you -- do you remember that? It was
4 in September of 2015.

5 A. Yes. I think that's the last time I
6 was here.

7 Q. In fact, you were in the same seat.

8 A. Probably. I don't -- I don't remember.

9 Q. Do you remember -- have you been
10 deposed in any mesh litigation since September of
11 2015?

12 A. I don't believe so.

13 Q. Have you testified in any trials
14 regarding mesh litigation since 2000 -- since
15 September 2015?

16 A. There was a Boston Scientific trial in
17 Statesville, North Carolina, in October.

18 Q. And you testified live in that trial?

19 A. Live?

20 Q. (Indicating yes.)

21 A. Yes.

22 Q. Are you still active in the
23 professional societies of American Institute of
24 Chemical Engineers?

1 A. Yes, I am.

2 Q. The Society for Biomaterials?

3 A. Yes.

4 Q. Research Society For Bone and Joint
5 Injectable Biomaterials?

6 A. Yes.

7 Q. I noticed that your expert report,
8 which is marked as Exhibit 2, doesn't include those
9 professional societies. Why not?

10 A. They're listed on my CV, which is part
11 of the report. I -- I don't know why. I just
12 didn't list them.

13 Q. Doctor, do you recall -- did you ever
14 read the deposition transcript from the Mullins
15 litigation?

16 A. I don't remember. I've -- I just don't
17 remember.

18 Q. Have any of your opinions changed since
19 you were deposed in the Mullins litigation?

20 A. No.

21 Q. What has been your total billing amount
22 that you have billed plaintiff attorneys since the
23 Mullins litigation?

24 A. Oh, in this particular case. I

1 submitted a bill for the report, for 10,000 for the
2 medium report.

3 Q. What about any charges for your time?

4 A. For this litigation? I don't think so.
5 Oh. No. This -- this is the only -- that was the
6 only one for this litigation.

7 Q. Have you done any additional work since
8 the Mullins deposition regarding mesh?

9 A. What do you mean by "work"? Do you
10 mean testing or reading? I'm not sure what you
11 mean.

12 Q. Well, any other work that you believe
13 is applicable to the mesh litigation since you were
14 deposed in Mullins in September 2015.

15 A. I -- I've not done any -- any testing.
16 I've done more reading, research. But I've not
17 done any testing since that time.

18 Q. What additional research have you done?

19 A. Reviewing the newer papers that were in
20 the report, reviewing the -- the Ethicon internal
21 documents, that sorts of activities.

22 Q. The "newer papers" that you're
23 referring to, are those contained in your expert
24 report?

1 A. I believe they are. Yes. That would
2 be -- yes, they are.

3 Q. Have you published any additional
4 articles?

5 A. On polypropylene mesh?

6 Q. (Indicating yes.)

7 A. No.

8 Q. Do you have any pending?

9 A. No.

10 Q. Have you worked on any since?

11 A. No.

12 Q. The last paper that you authored
13 regarding mesh was the one with Dr. Iakovlev
14 entitled "Degradation of Polypropylene in Vivo"?

15 A. Yes.

16 Q. Doctor, as we sit here today, are you
17 planning on doing any additional testing of mesh?

18 A. I don't know at this time. There are
19 no definite plans.

20 Q. Are you considering any additional
21 testing of mesh?

22 A. I am.

23 Q. All right. What are you considering?

24 A. Well, I don't -- I can't really answer

1 this question because it's a research project.

2 It's not part of these opinions in the litigation.

3 So it's -- I would call that a research project.

4 Q. Is it a research project for
5 litigation?

6 A. Not necessarily.

7 Q. So who is sponsoring the research
8 project?

9 A. Well, this is part of the work, as an
10 academic, is finding funding to support the work,
11 so. . . I don't -- I don't have any funding for it
12 right now.

13 Q. Okay. Are you -- but you're trying to
14 get funding for a research project?

15 A. I'm considering it, but I haven't done
16 anything definitive at this time.

17 Q. Have you asked anybody specifically for
18 funding?

19 A. No.

20 Q. Have you asked any plaintiff lawyer for
21 funding of this research project?

22 A. No.

23 Q. Can you give me just a general idea of
24 the research project that you're contemplating?

1 A. I'm really not comfortable doing that.
2 Just -- I -- I need to -- I just -- I don't -- I
3 don't think that would be good.

4 Q. Okay. Are you refusing to tell me?

5 A. "Refusing" is kind of a strong word. I
6 mean, I -- I don't want to discuss it in this
7 deposition. It's a research project that's outside
8 this litigation. So I -- to me it's not
9 something --

10 Q. Does it --

11 A. -- I -- I -- I would like to discuss
12 here.

13 Q. Does it relate to PROLENE mesh?

14 A. I don't know. I haven't -- I don't
15 know at this time.

16 Q. Does it relate to any of Ethicon's
17 products?

18 A. Again, at this time, I -- I don't know.

19 Q. Okay.

20 A. I haven't gotten that far.

21 Q. We talked about the IUGA meeting that
22 you went to in France --

23 A. Yes.

24 Q. -- back in -- in the summer of last

1 year; is that correct?

2 A. That's right.

3 Q. Have you attended any other
4 professional meetings since then regarding mesh?

5 A. Regarding mesh? No. Not that I can
6 remember.

7 Q. Were you ever reimbursed for your time
8 going to France for this meeting by the plaintiffs'
9 lawyers?

10 A. No.

11 Q. Did anybody ever compensate you for
12 your time?

13 A. So I -- I paid for my expenses
14 through -- through a fund I have at Vanderbilt that
15 I use for international travel.

16 Q. There was some discussion, if I recall,
17 about you submitting a research grant to the
18 National Institution of Health regarding mesh with
19 a Dr. Carey; do you remember that?

20 A. Yes. And for the record, can I just --
21 when you asked previously about who I have talked
22 with, she would be one that I discussed -- I just
23 forgot until you brought it up. Okay? I just --

24 Q. That's fine.

1 A. Yeah. For the record, Dr. Carey would
2 be another person that I've talked with.

3 Q. Okay. You can answer that question --

4 A. I'm sorry. Okay. Ask the question
5 again. I -- I -- I forgot.

6 Q. You discussed an idea about submitting
7 a research grant to the NIH regarding mesh with
8 Dr. Carey; do you remember that?

9 A. Vaguely. Yeah, I think it came up.

10 Q. What is -- what was the topic?

11 A. I don't remember.

12 Q. What's the status of it?

13 A. I haven't submitted anything.

14 Q. Okay. But what's the status of it?

15 A. What do you mean the status? Like --

16 Q. Where does it stand?

17 A. Well, as I was saying earlier, I just
18 haven't been working on it and I haven't drafted
19 anything. I haven't submitted anything. I
20 just. . .

21 Q. Was this the same research grant idea
22 that we discussed earlier?

23 A. I don't remember. I -- I don't
24 remember what I was talking with her about doing.

1 Q. Were you talking to her about doing
2 anything as it relates to mesh?

3 A. I just don't remember what I talked to
4 her about. It's been awhile, and I haven't really
5 acted on it. So I just -- I have lots of
6 discussions about new research projects. I -- I
7 just don't remember.

8 (Whereupon Exhibit 3 was marked as an
9 exhibit.)

10 BY MR. HUTCHINSON:

11 Q. I understand. I'll hand you what we've
12 marked as Exhibit 3 to your deposition.

13 A. Okay.

14 Q. This is the -- the paper that you
15 presented on at the meeting in France; is that
16 right?

17 A. Let me review it for -- briefly.
18 This -- this -- yes, this appears to be that
19 abstract that I submitted to the IUGA, and then I
20 presented on it at the IUGA meeting.

21 Q. And what contribution did Dr. Dunn
22 make?

23 A. So Dr. Dunn did the FTIR and the SEM
24 analysis. He and his student.

1 Q. And what did -- what contributions were
2 yours?

3 A. So my contributions were more on the
4 design of the experiment, the selection of the
5 oxidative medium, the -- those would have been my
6 contributions.

7 Q. Do you have any current or pending
8 experience with -- experiments with Dr. Dunn?

9 A. I do not.

10 Q. What about Dr. Iakovlev?

11 A. I do not.

12 Q. Do you have any current or pending
13 experiments regarding mesh with anyone, as we sit
14 here today?

15 A. No. I do not.

16 Q. Do you have any mesh explants in your
17 custody or control?

18 A. No.

19 Q. What about any pristine mesh exemplars
20 in your custody or control?

21 A. No.

22 Q. You don't have any mesh whatsoever
23 available to you in your custody or control?

24 A. No.

1 Q. Do you still defer to Dr. Dunn on the
2 interpretations of the FTIR spectra?

3 A. I do.

4 Q. And you disclosed this work in the
5 Perry litigation, didn't you? That was for TVT
6 ABBREVO?

7 A. The ABBREVO would be another product.
8 Yes.

9 Q. And you attempted to rely on this paper
10 in the Perry litigation, didn't you?

11 MR. BOWMAN: Object to form.

12 THE WITNESS: I -- I just don't
13 remember. It may have been on the -- on the -- on
14 the reliance list, but I don't -- I know it came up
15 in the deposition, but I deferred to Dr. Dunn for
16 the experimental details in the deposition. That's
17 what I remember.

18 BY MR. HUTCHINSON:

19 Q. Did you rely on this, Doctor, in
20 forming your opinions in the Perry litigation
21 regarding TVT ABBREVO?

22 A. I don't believe so. I mean, my
23 opinions have not changed in some time. So this
24 was supplemental information that supported my

1 opinion, but -- and it was on the reliance list
2 but -- I think it was. I just -- I can't remember
3 the details.

4 Q. Doctor, you relied on this work, that
5 we've marked as Exhibit 3 to your deposition, in
6 the Winebarger versus Boston Scientific litigation;
7 is that correct?

8 A. Winebarger? What product was this? I
9 can't remember the names -- the plaintiff name.

10 Q. It was a lawsuit styled Winebarger,
11 W-i-n-b-a-r-g-e-r, versus Boston Scientific.

12 A. That name just doesn't sound -- was it
13 part of a wave? Was it -- I just don't remember
14 the plaintiffs' names probably.

15 Q. Do you recall relying on this work that
16 was marked as Exhibit 3 in the Winebarger versus
17 Boston Scientific litigation?

18 A. I don't. Because I don't recall the
19 litigation. I just -- I don't -- the -- the
20 plaintiff's name is -- that doesn't sound familiar
21 to me.

22 Q. Okay. Doctor, when we look at Exhibit
23 3, what product was used in your work?

24 A. It's been some time. I don't remember.

1 These were sutures. I -- I -- we did -- no. No.
2 This was mesh. This was -- this was mesh. I -- I
3 don't remember the actual product that we were -- I
4 mean, it's been some time. I think there was a --
5 I think there was -- I think it was -- there were
6 definitely two Boston Scientific meshes, maybe the
7 Pinnacle. There were slings. Maybe the TV -- I
8 think the TVT, too.

9 Q. So you used a TVT and a Pinnacle device
10 in your work --

11 A. Perhaps --

12 Q. -- regarding oxidative degradation of
13 polypropylene in pelvic mesh in vivo attached as --
14 I mean, marked as Exhibit 3 to your deposition? Is
15 that your testimony, sir?

16 A. That's what I remember. I didn't -- I
17 mean, I wasn't -- yeah, I wasn't -- I'd have to
18 review this. But I believe it was a TVT and two
19 Boston Scientific meshes that were included -- I
20 just need to read -- can I read this again?
21 Because I can't remember, you know, exactly --

22 Q. Absolutely.

23 A. This was written two years ago
24 almost --

1 Q. Absolutely.

2 A. -- so I'm trying to remember exactly
3 what I wrote.

4 Q. And this was also presented a year ago,
5 correct?

6 A. Yes.

7 Q. Okay. So if you'll read through it and
8 tell me, sir, what the name of the products were
9 that were used in this experiment.

10 A. Okay. I can -- give me a minute
11 to. . .

12 Okay. So this was the mesh study.
13 Again, it's not stated in the abstract, but -- let
14 me just look at it again. (Reviews document.)

15 Okay. I -- I believe it was the TVT
16 and the Boston Scientific Advantage and Links,
17 maybe. It's just been so long, I -- I can't
18 remember the exact devices.

19 Q. So the products that you used were from
20 two different manufacturers, in this abstract; is
21 that correct, sir?

22 A. I believe so.

23 Q. Was the TVT mechanically cut or laser
24 cut?

1 A. I don't remember.

2 Q. How can you find out?

3 A. Dr. Dunn would have all that
4 information. He -- he had the mesh. He put it in
5 the medium. He was the one that physically did the
6 work. He and, I think, maybe one of his students
7 did some of it, but he -- he's the one that had the
8 exemplars and cut the samples and put them in the
9 medium. I didn't do that. And so --

10 Q. Okay.

11 A. And I never had the mesh in my
12 possession that I remember.

13 Q. Oh, you didn't. So, Doctor, can you
14 testify, to a reasonable degree of scientific
15 certainty, that the two products that were used in
16 this experiment were TVT and a Boston Scientific
17 product?

18 MR. BOWMAN: Object to form.

19 THE WITNESS: Again, I'm going based on
20 my memory.

21 BY MR. HUTCHINSON:

22 Q. I understand.

23 A. And --

24 Q. But I'd like for -- I'd like -- I need

1 an answer, based upon a reasonable degree of
2 scientific certainty. Can you testify today, to a
3 reasonable degree of scientific certainty,
4 regarding the specific names of the products used
5 in this experiment?

6 A. I mean, I believe, to a reasonable
7 degree of scientific certainty, that's what we --
8 that's what we used. That's what I remember. You
9 know, I work closely with Dr. Dunn. Our offices
10 are right beside each other. So, I mean, he --
11 he -- that's what I believe he did.

12 Q. Okay. And, Doctor, when you were
13 deposed in September in the Mullins litigation, you
14 didn't rely on this abstract for your opinions in
15 that; is that correct?

16 A. I don't believe so.

17 Q. And you're not relying on the abstract
18 that you published for your opinions in this
19 litigation; is that correct?

20 A. No, I'm not.

21 Q. Okay. Why not?

22 A. Well, we -- we -- we would like to
23 publish it. And that's something -- that's part of
24 what we're -- we -- we just -- we're -- we're

1 working on it. We don't know what we're going to
2 do yet. It's just -- you know, we have -- very
3 busy, and it's -- I don't -- I don't know what the
4 plan is. But I'm not relying on it because we
5 haven't published it.

6 Q. Okay. Any other reasons?

7 A. No. That's the main reason. I -- I
8 believe the Court likes to see published studies
9 and that's --

10 Q. Okay.

11 A. -- that -- that's our plan.

12 Q. But it's fair to say that you've
13 written a paper that investigated oxidative
14 degradation of polypropylene mesh in vitro using an
15 oxidative medium and you're not relying on that
16 work in this litigation?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: Can you repeat that? I'm
19 sorry.

20 BY MR. HUTCHINSON:

21 Q. Yes.

22 A. It was long.

23 Q. It's fair to say that you've written a
24 paper --

1 A. Okay.

2 Q. -- that investigated oxidative
3 degradation of polypropylene using an oxidated
4 medium and you're not relying on it in this
5 litigation; is that fair to say?

6 A. I would say it's a submitted abstract.
7 This is a submitted abstract. I wouldn't call this
8 a paper. It's a published abstract, and it is peer
9 reviewed but not like a paper. It's not -- I'm not
10 relying on it.

11 Q. And --

12 A. And that -- go ahead.

13 Q. What is the status of this work,
14 Doctor?

15 A. As I said, I -- I -- I don't know. We
16 don't know what we're going to do with it yet.

17 Q. When is the last time you talked to
18 Dr. Dunn about this?

19 A. I don't remember.

20 Q. Has it been more than six months?

21 A. Probably not. But I just don't -- I
22 don't remember what we said about this. We
23 haven't -- I haven't relied on it in the recent
24 litigation in some time. And it's -- you know,

1 it's just one of these unpublished studies that we
2 did, published an abstract, submitted at a meeting,
3 and just haven't followed up on it for the paper.
4 That's what I would say.

5 Q. Is this work finished?

6 A. Well, this study is finished. But when
7 you were asking me about research earlier, I -- I
8 mean, I -- I'm trying to be honest without
9 revealing, you know, what I consider to be, you
10 know, associated with my research being
11 confidential. But I don't know what we're going to
12 do next.

13 Q. Okay. But this study was finished,
14 correct?

15 A. This study is completed. Yes.

16 Q. Right. And this study was peer
17 reviewed in an abstract in the International
18 Urogynecology Journal, correct?

19 MR. BOWMAN: Object to form.

20 THE WITNESS: It was -- it was reviewed
21 for the meeting. I -- I wouldn't -- it's not --
22 yes, it was reviewed. Okay.

23 BY MR. HUTCHINSON:

24 Q. And, Doctor, were the chemical

1 conditions, to which you subjected the mesh,
2 intended to represent an actual in vivo condition
3 in the body?

4 A. So they were intended to simulate the
5 adherent macrophage pocket, the -- the space
6 between the adherent cell and the surface of the
7 material.

8 Q. I under - --

9 A. That's been published. Right? Yeah.

10 Q. I understand. But was it intended to
11 represent actual in vivo conditions in the body?
12 Yes or no?

13 A. Well, I thought I answered your
14 question. That would be the -- the -- it's
15 simulating that -- that situation where you have an
16 inherent macrophage attached to a biomaterial in
17 the body and there's a privileged microenvironment
18 between the cell and the material. And that medium
19 has been shown to -- published to simulate those
20 oxidative conditions between the cell and the
21 surface of the material.

22 Q. Are the chemical conditions intended to
23 represent actual in vivo conditions in the body,
24 sir? Yes or no?

1 A. I think I just answered the question.

2 Q. You didn't.

3 A. I did.

4 Q. I need "yes" or "no," and then you can
5 answer. . .

6 A. I can't give you a yes or no because
7 I -- I feel like you're trying to put -- I need to
8 be very specific about what that medium is
9 simulating.

10 Q. Absolutely.

11 And my question to you, sir, is the
12 oxidative medium designed to represent the actual
13 in vivo conditions in the body? Yes or no?

14 A. But "actual in vivo conditions" is what
15 I'm hung up on. That's a very vague term. It
16 is -- it's meant to simulate the
17 microenvironment -- in vivo microenvironment that
18 the material is exposed to. That's what it's meant
19 to simulate. That's, I think, an answer to your
20 question. You're asking me -- that's my answer.

21 Q. Is that the best you can do?

22 A. That's the best I can do. I'm sorry.
23 I just -- I don't want to agree to some very
24 vaguely stated question.

1 Q. Doctor, do you write about in vivo
2 conditions in this abstract?

3 A. I'd have to read it again. (Reviews
4 document.)

5 Q. Let's look on the last page.

6 A. Okay.

7 Q. At the conclusion. "Oxidative
8 degradation of polypropylene pelvic mesh was
9 evidenced by chemical and physical changes under
10 simulated in vivo conditions."

11 A. Okay.

12 Q. Did you write that?

13 A. I wrote that.

14 Q. Okay. So my question to you, sir, are
15 the chemical conditions, to which you subjected the
16 mesh, intended to represent simulated in vivo
17 conditions in the body? Yes or no?

18 A. Yes. I wrote that. I stand by what I
19 wrote.

20 Q. All right. Since the Mullins
21 deposition, Doctor, have you done any work to
22 determine if oxidized polypropylene will stain?

23 A. Since the Mullins deposition last fall?

24 Q. Yes, sir.

1 A. No.

2 Q. Have you ever done any work in your
3 life to determine if oxidized polypropylene will
4 stain?

5 A. No.

6 Q. When is the last time you've spoken
7 with Dr. Iakovlev?

8 A. That's been some time. Maybe -- I need
9 to think for a minute. Probably last summer at the
10 meeting.

11 Q. Doctor, are you aware of any literature
12 that discusses the extent to which oxidized
13 polypropylene traps and holds stain?

14 A. Well, we discussed it in the paper with
15 Dr. Iakovlev, but I -- I'm not aware, at this
16 moment, off the top of my head, of another paper
17 that would -- I'd have to look at the paper again.
18 It's been some time.

19 Q. You testified in the Mullins deposition
20 that you've never done an XPS analysis. Does that
21 remain true?

22 A. I'd like to -- I've -- I've never
23 physically done it myself. My students have done
24 it. But I've never actually done the measurement.

1 Q. Have you ever done any molecular weight
2 testing of PROLENE?

3 A. Not of PROLENE.

4 Oh, I'm sorry. Can I --

5 Q. (Indicating yes.)

6 A. We -- we did some molecular weight
7 testing with Dr. Dunn on exemplars some time ago.
8 It's been a long time. And I don't remember if
9 PROLENE or TVT devices were included. I can't
10 remember the devices.

11 Q. Okay.

12 A. But we -- we sent those to another lab.
13 It was in one of his reports.

14 Q. What were the results?

15 A. I don't remember. I haven't been
16 relying on that, so I just don't remember.

17 (Reporter interruption for
18 clarification.)

19 THE WITNESS: You know, I'm. . .

20 BY MR. HUTCHINSON:

21 Q. Well, my question --

22 A. Yeah.

23 Q. I'm not sure I understood your answer.

24 Have you ever done -- have you personally ever done

1 any molecular weight testing of PROLENE?

2 A. Well, I'm trying to -- I'm trying to
3 answer. So -- I mean, I don't -- I mean, being a
4 professor, I don't actually work in the lab. I
5 have graduate students and a lab manager that do
6 the work that we discuss, right? And I -- I'm --
7 sort of direct of work, if you want to call it
8 that.

9 And what I -- what I was saying is that
10 some time ago, a couple years at least, we --
11 Dr. Dunn and I sent some samples to -- Dr. Dunn
12 handled the samples -- to another laboratory to do
13 molecular weight measurements. And whether PROLENE
14 meshes -- you know, meshes made out of PROLENE were
15 in those samples, I can't remember. It's been a
16 long time. So. . .

17 Q. Okay. And you don't know the results;
18 is that correct?

19 A. I don't remember the results.

20 Q. Doctor, have you ever done any
21 molecular weight testing of PROLENE explants?

22 A. I don't think so. The samples -- no, I
23 don't think so.

24 (Whereupon Exhibit 4 was marked as an

1 exhibit.)

2 BY MR. HUTCHINSON:

3 Q. Doctor, handing you what we'll mark as
4 Exhibit 4 to your deposition --

5 A. Okay.

6 Q. -- you cite this on page 9 of your
7 expert report. Do you remember that?

8 A. Yes.

9 Q. Okay. And, in fact, if you look on
10 your expert report, under "Summary of Opinions,"
11 Number 7.

12 A. Okay.

13 Q. It's on page 3. It states --

14 A. Okay.

15 Q. -- ". . .the use of heavy-weight meshes
16 directly correlates with more exposure of
17 polypropylene to the Foreign Body Reaction and
18 greater changes after implantation. . ."

19 Do you see that?

20 A. Yes.

21 Q. All right. Doctor, how do you define
22 "heavy-weight"?

23 A. My understanding is that the TVT mesh
24 has a weight of around -- a surface density of

1 around 100, would be a heavy-weight mesh.

2 Let me look at this paper again for a
3 minute. I believe it was discussed in here, the
4 densities of the specific meshes that she tested.

5 Yeah. So this would be the GYNEMESH
6 that had a density of 44 grams to square meter;
7 ULTRAPRO, which was 31; and Restorelle was 19.

8 Q. Doctor, how do you define
9 "heavy-weight"?

10 A. How do I define "heavy-weight"?

11 Q. Yes, sir.

12 A. I think -- I think something greater
13 than 50 grams per square meter would be a heavier
14 weight mesh.

15 Q. And how do you come up with the number
16 50 grams per square meter?

17 A. I -- I can't remember. There's some
18 papers -- there's a paper where this is -- these
19 are classified, and I just can't remember the
20 numbers right now.

21 Q. Well, you mean you can't remember the
22 cite right now?

23 A. Yeah. Well, the -- I can't remember
24 the citation, and I can't remember the actual

1 ranges that were listed in the -- in the table.

2 I'd have to look at this --

3 Q. I understand. But, Doctor, sitting
4 here today, and one of your opinions on Number 7 is
5 the -- is about heavy-weight meshes. So my
6 question to you is --

7 A. Okay.

8 Q. -- how do you define a heavy-weight
9 mesh?

10 A. So a heavy-weight mesh would be a mesh
11 in the range of -- I'd probably say 100 grams per
12 square meter. Those are the heavy-weight meshes
13 that -- in my recollection.

14 Q. Okay. And if something is less than
15 100 grams per square meter, according to your --
16 your definition, would that be a light-weight mesh?

17 A. No. I don't think I would call it a
18 light-weight mesh. I mean, what I was really
19 trying to say in this opinion is that the more
20 polypropylene is there, the more intense the
21 foreign body reaction. That's what the point of
22 that opinion is.

23 Q. Right. But my --

24 A. So it's a sliding scale. I mean --

1 right? I mean, as the density increases, it's
2 going to be more intense. That's what I was
3 saying.

4 Q. Right. My question to you, sir, is how
5 do you define a heavy-weight mesh? Is it something
6 greater than 50 -- I'm sorry -- something greater
7 than a 100 grams per meter squared? Is that
8 Dr. Guelcher's definition?

9 MR. BOWMAN: Object to form.

10 THE WITNESS: Again, there's lots of
11 different definitions of polypropylene mesh. 100
12 grams per square meter is -- I would consider that
13 to be a heavy-weight mesh.

14 BY MR. HUTCHINSON:

15 Q. Okay. And if something is less than
16 100 grams per square metered, would that be a
17 medium-weight mesh or a light-weight mesh? What
18 would it be?

19 A. I don't -- I don't know specifically.
20 I mean, everybody has a different range that they
21 use to define that. I don't -- I mean, there's not
22 a lot of -- there's not a lot of agreement in the
23 literature.

24 Q. You can't tell me whether or not

1 something would be a light-weight mesh if it was
2 less than 100 grams per meter squared; is that
3 correct?

4 A. Some would call that a -- a
5 light-weight mesh --

6 Q. All right.

7 A. -- if it's less than 100.

8 Q. Do you -- do you, Doctor, as a polymer
9 scientist and as an expert in this litigation, have
10 a definition for a light-weight mesh?

11 A. No. Because I was looking at it from
12 the perspective of the amount of polypropylene
13 increases with mesh density. It's not just a
14 simple classification, as the mesh increases, the
15 foreign body reaction increases, because it's
16 dependent on that surface of polypropylene. That's
17 what I'm saying.

18 Q. Are you aware of any medical device
19 industry standard that measures or defines
20 heavy-weight mesh?

21 A. Industry standard? I -- I'm -- I -- I
22 think that's what I was saying. There's different
23 investigators and maybe companies who have
24 defined -- but it's -- it's not -- I don't -- I

1 don't -- I guess what I'm saying is I don't
2 consider it a -- something that's agreed upon, say,
3 like in an ASTM standard. It's somewhat
4 discretionary, I would say.

5 Q. All right. So you're not aware of any
6 medical device industry standard that measures or
7 defines heavy-weight mesh; is that correct?

8 A. There may be a standard that mesh -- I
9 can't think of it right now. I -- I can't
10 remember.

11 Q. Okay. Doctor, are you aware of any
12 medical device industry standard that measures and
13 defines pore size?

14 A. I mean, pore size isn't really what I
15 was talking about in my opinions. So that's not
16 something --

17 Q. All right. I can cut to the chase.

18 A. Okay.

19 Q. Do you have any opinions whatsoever
20 regarding the pore size of the PROLENE mesh
21 contained in any of the products that you're giving
22 opinions about today?

23 MR. BOWMAN: Object to form.

24 BY MR. HUTCHINSON:

1 Q. We can short circuit that.

2 A. Okay. Let me just think for a second.

3 So I -- I don't believe that I
4 discussed pore size in my report.

5 Q. Is it fair to say, Doctor, you have no
6 opinions regarding pore size of the mesh of the
7 products that you're here to give testimony about
8 today; is that right?

9 MR. BOWMAN: Object to form.

10 THE WITNESS: Maybe other than it could
11 change in the mechanical environment and in the
12 chemical changes that happen to the mesh, pore size
13 could change, that could affect infiltration.

14 BY MR. HUTCHINSON:

15 Q. Is that an opinion you're going to
16 stand by today?

17 A. I don't believe so. It's not in my
18 report.

19 Q. Okay. Thank you.

20 So fair so say you have no opinions
21 regarding pore size on the products that you're
22 designated to give testimony about today?

23 MR. BOWMAN: Object to form.

24 THE WITNESS: I think so. I'm not

1 discussing pore size in the report.

2 BY MR. HUTCHINSON:

3 Q. Okay. Well, Doctor, what is your
4 opinion regarding the ideal weight of mesh?

5 A. I don't believe I've expressed an
6 opinion about the ideal weight. My opinion has
7 been the more mesh, the more intense the foreign
8 body reaction. So I haven't really expressed an
9 opinion about ideal weight.

10 Q. Okay. Do you have an opinion, as we
11 sit here today, regarding the ideal mesh -- mesh in
12 terms of weight?

13 A. It would help me if you could be
14 specific. I -- I -- I'm not saying that there's an
15 ideal weight for the mesh. All I'm saying is that
16 the intensity of the foreign body reaction
17 increases with the weight density of the mesh.
18 That's -- and I'm not saying that that should be 30
19 or it should be 20. I'm saying that -- it's -- as
20 the amount of polypropylene increases, the
21 intensity of foreign body reaction. That's --
22 that's what I'm saying.

23 Q. Okay. But can you tell us -- can you
24 tell us the ideal weight of the mesh?

1 A. No. I've not testified about an ideal
2 weight of mesh.

3 Q. Doctor, you'll agree that any implanted
4 material will elicit some form of foreign body
5 reaction or inflammatory response?

6 A. Yes. That's a foreign body reaction.
7 When a material is implanted, it induces and
8 elicits a foreign body reaction.

9 Q. And the microphage's response is an
10 essential component of tissue incorporation,
11 correct?

12 A. What do you mean by "essential"? I'm
13 not --

14 Q. You must have a microphage response to
15 have tissue incorporation in the mesh, correct?

16 A. Well, macrophages infiltrate the mesh
17 like they do any foreign body. It just happens.
18 It's not -- it's not necessarily something that can
19 be controlled. It just happens. It's a foreign
20 body reaction.

21 Q. Let's look at the Moalli paper --

22 A. Okay.

23 Q. -- that we've marked --

24 A. Okay.

1 Q. -- Exhibit 4. Are you there with me?

2 A. I am.

3 Q. This paper studied two meshes with

4 PROLENE: GYNEMESH PS and ULTRAPRO; is that right?

5 A. Yes. I believe so.

6 Q. And this is the one of the newer papers
7 that you're relying on; is that correct?

8 A. It is.

9 Q. What does GYNEMESH PS stand for?

10 A. I -- I don't remember the PS. I know
11 that the GYNEMESH is -- is -- I believe it's used
12 in the POP kits. It's a lower-density mesh than
13 the TVT. I don't know what the PS -- I'd have to
14 look at the paper again. I don't. . .

15 Q. All right. It's on page 1 under
16 "Results," last paragraph. They compare ULTRAPRO
17 with Restorelle --

18 A. Uh-huh.

19 Q. -- and GYNEMESH PS. Do you see that?

20 A. I do.

21 Q. My question, Doctor, is what does the
22 PS in GYNEMESH stand for?

23 A. I -- I just don't remember.

24 Q. Did you make any effort to find out?

1 MR. BOWMAN: Object to form.

2 THE WITNESS: I don't remember. I was
3 looking at the density in the table. I don't know
4 the specific formulation of that --

5 BY MR. HUTCHINSON:

6 Q. Do you know how GYNEMESH PS may be
7 different than GYNEMESH?

8 A. I -- I -- I -- I don't remember how
9 it's different from GYNEMESH.

10 Q. Do you have any idea, as we sit here
11 today, what the PS stands for?

12 MR. BOWMAN: Object to form. Asked and
13 answered.

14 THE WITNESS: I mean, it's a company
15 acronym. I don't -- I don't know why they call it
16 a GYNEMESH PS. I don't remember.

17 BY MR. HUTCHINSON:

18 Q. Do you know if it's 100 percent
19 PROLENE?

20 A. I'd have to look at this again. I
21 can't remember. One of these was -- maybe it was
22 the Restorelle that had a -- had a resorbable
23 component I thought.

24 Q. Right. Let's talk about GYNEMESH PS.

1 Do you know if the mesh made in GYNEMESH PS is 100
2 percent PROLENE?

3 A. I mean, I believe it is. They -- they
4 say the -- we sought to determine the predominant
5 cell type within the area of implantation of the
6 prototypical polypropylene mesh, GYNEMESH PS.

7 Q. ULTRAPRO has an absorbable component,
8 doesn't it?

9 A. It's my understanding there's a
10 resorbable polyester component. Wait a minute.
11 Let me look at my report again. I can't. . .

12 Yeah, so the PROLIFT, I know, has
13 the -- the resorbable component. But she says
14 these are polypropylene meshes in the objective.
15 So that's what I read it, is that these are
16 polypropylene meshes with different densities.
17 That was what I understood to be the -- the purpose
18 of this study.

19 Q. Doctor -- Doctor, do you know the
20 weight of the adsorbable component in ULTRAPRO?

21 MR. BOWMAN: Object to form.

22 THE WITNESS: I -- I don't remember
23 right now.

24 BY MR. HUTCHINSON:

1 Q. Let's talk about the -- the products
2 that you're designated for. I will represent to
3 you, Dr. Guelcher, and also represent to the Court
4 that you've been designated for -- to give opinions
5 for TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT EXACT,
6 PROSIMA, GYNEMESH PS, PROLIFT, and PROLIFT+M. Have
7 you heard of all those products?

8 A. I have.

9 Q. Okay.

10 THE WITNESS: Can we take a break for a
11 few minutes? My stomach's a little bit -- is that
12 okay?

13 MR. HUTCHINSON: Yes, sir.

14 THE WITNESS: Thank you.

15 (Brief recess.)

16 BY MR. HUTCHINSON:

17 Q. Dr. Guelcher, are you okay?

18 A. Yeah. I'm okay.

19 Q. All right. If you need to take another
20 break, let me know. Okay?

21 A. Okay. Thanks.

22 Q. Doctor, do you know the weight of
23 TVT-O?

24 A. The weight? The density?

1 Q. In grams -- yes. In grams per meter
2 squared.

3 A. I believe it's similar to the TVT,
4 which is around 100.

5 Q. What about TVT ABBREVO?

6 A. I think it's similar. I think it's
7 made from the same mesh.

8 Q. Do you -- but do you know the weight,
9 sir?

10 A. 100.

11 Q. Do you know the weight of TVT-SECUR?

12 A. Let me look back at my report.
13 Again -- well. . . (Reviews document.)

14 Yeah. So it's in my report. The --
15 the -- those SUI devices, the slings, the TVT-S,
16 TVT ABBREVO, TVT-O, TVT are made from this
17 105-gram-per-square-meter mesh. So they're all
18 made from the same mesh, in my understanding.

19 Q. And -- and, Doctor, is it your
20 testimony for all TVT products the weight of the
21 mesh per meter squared is the same?

22 A. That's my understanding --

23 Q. All right. Doctor --

24 A. -- for the slings.

1 Q. And, Doctor, for the POP products, do
2 you know the weight of the mesh per meter squared?

3 A. I don't remember them all. The
4 GYNEMESH is 45 grams per square meter. The -- the
5 PROLIFT+M, that's the one that's the blend, has the
6 resorbable polyester. After the polyester resorbs,
7 the density is 28. So it's probably, roughly, you
8 know, half, something in that range. So as the
9 polyester resorbs, the density goes down.

10 Q. And, Doctor, if we look at the Moalli
11 paper --

12 A. Okay.

13 Q. -- that you have, the mesh didn't
14 oxidize after 12 weeks, did it?

15 A. Well, she wasn't testing for oxidation.
16 She was looking at the cellular response. So I
17 wouldn't say that it didn't oxidize. I just -- I
18 don't think she reported that it did. But I don't
19 know that she really did any testing for that.

20 Q. A causal relationship wasn't
21 established in that paper, was it, sir?

22 A. A causal relationship --

23 Q. Correct --

24 A. -- between what?

1 Q. The weight of the mesh and clinical
2 problems; is that correct?

3 A. Well, this wasn't really addressing
4 that question. The -- the relationship was between
5 the density of the mesh and the nature of the
6 inflammatory infiltrate. That was the question she
7 was looking at. It wasn't related. This was a
8 preclinical study, I believe. So it wasn't -- this
9 was in Rhesus macaque. So it wasn't --

10 (Reporter interruption for
11 clarification.)

12 THE WITNESS: Rhesus macaque, which is
13 the -- it's a -- it's a primate. So it's not a
14 clinical study.

15 BY MR. HUTCHINSON:

16 Q. There were a number of limitations in
17 that study, weren't there?

18 A. So she has a paragraph in the
19 discussion about limitations of the study, which is
20 typical in scientific research. That's what we do.

21 Q. Okay. And, Doctor, if we look back at
22 your expert report --

23 A. Okay.

24 Q. -- under "Summary of Opinions" --

1 A. Okay.

2 Q. -- Number 1 --

3 A. So we -- okay. Go ahead. Sorry.

4 Q. Number 1 discusses "polypropylene
5 reacts with molecular oxygen by autoxidation
6 outside the body at elevated temperatures,
7 resulting in chain scission and deterioration. . ."

8 Do you see that?

9 A. Yes.

10 Q. At what elevated temperatures outside
11 the body?

12 A. I have to look at the details again.
13 Temperatures above 100 C. That is 100 Celsius.

14 Q. And -- and what is the normal body
15 temperature in Celsius degrees of the human body?

16 A. 37.

17 Q. And what is autoxidation, Doctor?

18 A. Well, "autoxidation" is a term that
19 some use to describe the reactive -- the reaction
20 of the polypropylene with molecular oxygen at
21 elevated temperatures.

22 Q. And we don't have elevated temperatures
23 in the body, in vivo, do we, to the point where it
24 would autoxidate?

1 MR. BOWMAN: Object to the form.

2 THE WITNESS: Well, the body
3 temperature is 37 degrees C. So that reaction with
4 molecular oxygen would be slow. I mean. . .

5 BY MR. HUTCHINSON:

6 Q. In fact, have you quantified how slow
7 it would be?

8 A. Well, I mean, Leibert addressed that
9 question with molecular oxygen.

10 Q. But my question to you, sir, is have
11 you personally quantified that?

12 A. No. Because I don't think it's
13 relevant because there's more reactive forms of
14 oxygen in the body that are causing the reaction.
15 So. . .

16 Q. What is -- what is required for PROLENE
17 to undergo autoxidation?

18 A. Well, PROLENE will undergo oxidation
19 with molecular oxygen. It -- it -- it can happen
20 at lower temperatures. It's just very, very slow.

21 Q. Okay.

22 A. So, I mean, it happens faster. Like
23 any chemical reaction --

24 Q. I understand.

1 A. -- it's -- it's faster at higher
2 temperatures.

3 Q. But what is required for PROLENE to
4 undergo autoxidation in the body?

5 A. In the body? You're asking a different
6 question. I'm confused.

7 Q. I am.

8 A. Okay.

9 Q. In general, what is -- strike that.

10 A. Okay.

11 Q. In general, what is required for
12 PROLENE to undergo autoxidation?

13 A. A -- I thought I answered it. It's --
14 again, it would be the reaction with molecular
15 oxygen is happening at faster rates at higher
16 temperatures.

17 Q. Okay.

18 A. In -- in -- under body conditions, that
19 reaction with molecular oxygen would be slow.

20 Q. And --

21 A. That's what I said.

22 Q. And at what temperature, Doctor,
23 would --

24 A. Well, I mean, at what temperature -- it

1 increases with temperature.

2 Q. Okay.

3 A. As the temperature gets higher, it gets
4 faster.

5 Q. Can you -- can you tell me a
6 temperature for PROLENE to undergo autoxidation?
7 Can you tell me a specific temperature?

8 MR. BOWMAN: Object to form.

9 THE WITNESS: Well, I'm trying to
10 answer. I -- I mean, it -- it's a chemical
11 reaction. And the Arrhenius equation tells us that
12 these reactions get faster as the temperature goes
13 up. So the reaction can occur at physiological
14 temperatures. It's just very slow.

15 People do the studies at higher
16 temperatures because they want to do them quickly.
17 So if you increase the temperature to 100 degrees
18 or 200 degrees Celsius, the reaction is faster.
19 And that's why a lot of these older studies did it
20 at higher temperatures.

21 BY MR. HUTCHINSON:

22 Q. Right. But my question is what
23 temperature is required for PROLENE to undergo
24 autoxidation?

1 A. I'm really trying to answer it. I
2 mean, it's a chemical reaction. It -- it -- it --
3 PROLENE is polypropylene with antioxidants. And
4 the antioxidants can delay the reaction, but,
5 eventually, it's going to happen. So. . .

6 Q. At what rate -- excuse me.

7 A. Go ahead. I -- I'm finished.

8 Q. At what rate does PROLENE undergo
9 autoxidation in the body?

10 A. I don't know the rate. I've not
11 measured it. But I wasn't really -- no. I don't
12 know the rate that -- that thermal oxidation is
13 going to. . .

14 Q. If we -- if we look at the summary of
15 opinions, Number 3 --

16 A. Okay.

17 Q. -- you discuss the dynamic environment
18 where polypropylene mesh is implanted. Do you see
19 that opinion?

20 A. Yes.

21 Q. What scientific evidence do you have,
22 Dr. Guelcher, for chain scission having occurred
23 with PROLENE in vivo?

24 MR. BOWMAN: Object to form.

1 THE WITNESS: Well, I mean, the paper
2 published in 2015 by Mays, et al., showed
3 reductions in molecular weight. Now, that wasn't
4 PROLENE, but it was still polypropylene with
5 antioxidants.

6 BY MR. HUTCHINSON:

7 Q. Okay.

8 A. It's very similar material.

9 Q. Okay. Let's -- let's focus on PROLENE,
10 though, Doctor.

11 What scientific evidence do you have
12 for chain scission having occurred with PROLENE in
13 vivo?

14 MR. BOWMAN: Object to form.

15 THE WITNESS: PROLENE in vivo. I don't
16 know of a study that specifically looked at chain
17 scission of PROLENE in vivo.

18 BY MR. HUTCHINSON:

19 Q. And, Doctor, what scientific evidence
20 do you have for any PROLENE implant having oxidized
21 to produce a carbonyl group, a C double bond O?

22 A. Can we go back to the chain scission
23 one? I just remembered something or -- or I need
24 to answer this first.

1 Q. Well, let's stick with this one.

2 A. Okay. So can you say it again?

3 Q. What scientific evidence do you have
4 for any PROLENE implant having oxidized to produce
5 a carbonyl group?

6 A. Let me look at my report again. There
7 was some studies done at Ethicon that reported
8 oxidation. And I'm trying to remember the details
9 of exactly what they reported. I -- I believe they
10 saw in those -- in those -- let me read my report
11 again because I'm -- I'm. . . (Reviews document.)

12 So there were some studies by Dr. Moy
13 that noted the presence of oxidation products by
14 FTIR. I believe that was incubated in hydrogen
15 peroxide. There were some human explants where
16 they observed degradation. And this question of
17 oxidation of the materials was referred to in those
18 studies.

19 Q. Okay.

20 A. They found that the cracked PROLENE
21 surface is a composite of oxidized polypropylene,
22 an adsorbed protein. So there was some internal
23 Ethicon studies that looked at these questions of
24 antioxidant depletion, oxidation of the surface,

1 cracking, and molecular weight degradation.

2 Q. Outside of Ethicon's internal
3 studies --

4 A. Okay.

5 Q. -- are you aware of any scientific
6 evidence that a PROLENE implant has oxidized to
7 produce a carbonyl group?

8 MR. BOWMAN: Object to form.

9 THE WITNESS: So Clavé addressed --
10 BY MR. HUTCHINSON:

11 Q. Okay.

12 A. No. Clavé didn't -- he didn't -- he
13 just says that he tested these different explants.
14 So he doesn't necessarily divide it out by
15 manufacturer, so it's --

16 Q. I understand.

17 A. -- it's not totally clear, right?

18 Q. Okay.

19 A. But, I mean, he does say -- he does
20 observe evidence -- I've talked about this
21 before -- evidence in the FTIR spectrum that I
22 believe is indicative of oxidation. I know it's --
23 we talked about this before. I don't --

24 Q. Are you basing this solely on Clavé?

1 A. Clavé would be the one that -- I think
2 Céline Mary discussed this as well.

3 Q. Okay. And is that the only scientific
4 evidence that you're relying on is Clavé and the
5 internal Ethicon documents for a PROLENE implant
6 having oxidized to produce a carbonyl group?

7 MR. BOWMAN: Object to form.

8 THE WITNESS: Those are the documents
9 that come to mind that I've testified about before.

10 BY MR. HUTCHINSON:

11 Q. Okay. Doctor, do you have -- and let's
12 talk about -- my question is very specific as it
13 relates to the nine specific products that you're
14 here to give testimony about.

15 A. Okay.

16 Q. TVT, TVT-O, TVT ABBREVO, TVT-SECUR, TVT
17 EXACT, PROSIMA, GYNEMESH PS, PROLIFT, and
18 PROLIFT+M. Okay?

19 A. Yes.

20 Q. So my question, when I talk about the
21 nine products, that's what I'm talking about.

22 A. I understand.

23 Q. All right. Do you have any scientific
24 evidence that any of those nine products were

1 implanted and oxidized to produce a carbonyl group?

2 A. Again, the only study that could have
3 included those devices would be the Clavé study
4 where he took the 100 explants. And also the study
5 with Dr. Iakovlev, but that was looking more at --
6 that was explanted mesh as well, that looked at the
7 degradation layer. But not -- well, he did look at
8 the question of oxidation indirectly with the
9 myeloperoxidase staining that we saw.

10 Q. Right. But not specifically for those
11 nine products, correct?

12 A. Those nine products were not
13 specifically mentioned in the Iakovlev study that I
14 remember.

15 Q. Thank you.

16 So the only -- the only paper that
17 you're relying on as it relates to whether any of
18 those nine products oxidized to produce a carbonyl
19 group, after it was implanted in vivo, is the Clavé
20 study; is that correct?

21 MR. BOWMAN: Object to form.

22 THE WITNESS: For those nine products,
23 that would be the one that I would. . .

24 BY MR. HUTCHINSON:

1 Q. That would be the one that you would
2 what?

3 A. I'm just thinking. I'm sorry. I'm
4 just thinking. You're -- you're referring
5 specifically to the question of the carbonyl bond
6 and the oxidation, right?

7 Q. (Indicating yes.)

8 A. Yeah. That would be the one that would
9 come to mind.

10 Q. Okay.

11 A. That's the one I would rely on.

12 Q. Okay. And Clavé is the same one that
13 you rely on that states that the FTIR could
14 neither -- neither confirm nor rule out oxidation,
15 correct?

16 A. Clavé states that.

17 Q. Yes.

18 A. I don't necessarily agree with it. But
19 that's what the paper says.

20 Q. And, Doctor, going back to these nine
21 products, do you have any evidence that any of
22 these nine products became embrittled in vivo?

23 MR. BOWMAN: Object to form.

24 THE WITNESS: I mean, again, in the

1 Iakovlev study, we -- there were a lot of explants,
2 but they weren't specifically named. They were
3 slings, POPs, maybe some hernia mesh, too. But
4 they -- the products weren't specifically named.
5 So I -- I -- I can't -- I mean, it was a number of
6 devices, right?

7 BY MR. HUTCHINSON:

8 Q. Yeah.

9 A. Not -- not -- those specific products
10 were not named.

11 Q. Right. So I'm not asking about whether
12 or not Iakovlev named them. My question to you,
13 sir, is do you have any scientific evidence that
14 any of those nine products have become embrittled
15 in vivo?

16 MR. BOWMAN: Object to form.

17 THE WITNESS: Again, not direct -- what
18 did you say? Embrittled? I mean, there's no
19 direct evidence that those specific products has
20 been published.

21 BY MR. HUTCHINSON:

22 Q. And nor do you have any scientific
23 evidence that any of those nine products have
24 become embrittled, do you?

1 MR. BOWMAN: Object to form.

2 THE WITNESS: I guess I'm a little hung
3 up on scientific evidence. I mean, you mean
4 directly measured, right? Reported?

5 BY MR. HUTCHINSON:

6 Q. (Indicating yes.)

7 A. I mean, I believe -- well, you know my
8 opinions. But I --

9 Q. Well, I'm trying to find out your
10 opinions.

11 A. Okay.

12 Q. So my opinions are -- that's the goal
13 of today.

14 A. No. I understand. But -- okay. So
15 I'll state it again. I mean, I believe -- I don't
16 want to argue about it. I mean, I believe that
17 those devices are made of polypropylene, which
18 these fundamental chemical reactions apply to.
19 Now, has anyone specifically measured it for those
20 devices? I -- I -- I don't know that that's been
21 reported, but I believe the body of scientific
22 evidence says that that's what's happening. That's
23 my opinion. Okay?

24 Q. But my question to you, do you know of

1 any scientific evidence, as we sit here today, that
2 any of those nine products have become embrittled
3 in vivo?

4 A. Again, I'm hung up on the scientific
5 evidence. I mean, I -- I believe there's
6 evidence --

7 MR. BOWMAN: Object to the form.

8 THE WITNESS: Okay.

9 I don't know how to answer that. I
10 mean, I --

11 BY MR. HUTCHINSON:

12 Q. Have you ever used the word "scientific
13 evidence" as a polymer scientist?

14 A. Well, I mean, it's a word. I mean, I
15 know this word. But it can mean lots of things to
16 lots of people, right?

17 Q. Okay.

18 A. Like anything.

19 Q. So my --

20 A. So I -- I'm just -- I'm just saying
21 like a direct measurement of that phenomenon,
22 I've -- I've not seen published.

23 Q. Okay. You've not seen published it.

24 A. Yeah.

1 Q. Nor are you aware of any evidence that
2 any of those nine products, specific products, have
3 become embrittled in vivo, are you?

4 MR. BOWMAN: Object to form.

5 THE WITNESS: Again, I've not seen
6 anybody actually measure that, I mean, if that's
7 what you're. . .

8 BY MR. HUTCHINSON:

9 Q. And you haven't measured that, have
10 you?

11 A. No.

12 Q. And, Doctor, are you aware of any
13 scientific evidence that any of those nine products
14 have lost molecular weight in vivo?

15 MR. BOWMAN: Object to form.

16 THE WITNESS: For those nine specific
17 products, no one has shown -- published that they
18 lose molecular weight.

19 BY MR. HUTCHINSON:

20 Q. And are you aware, personally, of any
21 evidence that any of those nine specific products
22 have lost molecular weight in vivo?

23 A. Could you rephrase that? I didn't --

24 Q. Are you personally aware of any

1 evidence that any of those nine specific products
2 have lost molecular weight in vivo?

3 A. Again, no direct measurements of that.

4 Q. And, Doctor, are you aware -- other
5 than Clavé, are you aware of any literature that
6 shows PROLENE produced a carbonyl group after it
7 was implanted?

8 A. Let me look at my report again. I know
9 Mary was looking at -- Céline Mary did the PROLENE
10 implant study with Guidoin.

11 (Reporter interruption for
12 clarification.)

13 THE WITNESS: Guidoin, G-u-i-d-o-i-n.

14 I just need to review what I wrote about that.

15 (Reviews document.)

16 Could you repeat the question? I'm --
17 I'm sorry. I'm -- I'm not feeling well. I forgot
18 it. I -- could you repeat the question, please?

19 Oh, you're going to read it? Okay.
20 That's fine.

21 BY MR. HUTCHINSON:

22 Q. I can remember it. Other than Clavé,
23 are you aware of any literature that shows PROLENE
24 produced a carbonyl group after it was implanted?

1 A. Okay. I just need to find where I
2 wrote about Céline Mary to answer that question.
3 (Reviews document.)

4 Q. But you would -- but other than Céline
5 Mary, are you aware of any literature?

6 A. Carbonyl and PROLENE due to oxidation.

7 Q. After it was implanted.

8 A. After it was implanted --

9 Q. Yes, sir.

10 A. -- in PROLENE. (Reviews document.) I
11 can't think of anything other than those two
12 studies.

13 Q. Doctor, have you ever examined an
14 explant of PROLENE from a patient?

15 A. With Dr. Dunn, yes. And Dr. Iakovlev.

16 Q. Was it -- what type of PROLENE explant
17 was it?

18 A. Oh, PROLENE.

19 Q. Oh, I'm sorry. Maybe you might --
20 might not have understood my question.

21 A. I -- I --

22 Q. Let's make sure the record's clear.

23 A. I miss -- yeah.

24 Q. That's fine. Don't worry about it.

1 Have you ever examined a PROLENE
2 explant from a patient?

3 A. Not specifically PROLENE.

4 Q. Sitting here today, do you have any
5 evidence that a PROLENE explant has failed in the
6 patient?

7 MR. BOWMAN: Object to the form.

8 THE WITNESS: Wow. Failed. What do
9 you mean by "failed"? That's a -- could mean a lot
10 of things. So what do you mean -- can you be more
11 specific about failed?

12 BY MR. HUTCHINSON:

13 Q. It didn't do what it was intended to
14 do.

15 MR. BOWMAN: Object to form.

16 THE WITNESS: Are you talking about
17 mesh or sutures? I'm -- I -- it just seems like a
18 broad question.

19 BY MR. HUTCHINSON:

20 Q. Right.

21 A. If you could --

22 Q. You're here about -- you're here about
23 nine mesh products, correct?

24 A. Yes.

1 Q. All right.

2 A. Because you keep saying PROLENE and
3 mesh. I'm just getting confused.

4 Q. All right. Have you ever examined --
5 strike that.

6 Do you have any scientific evidence
7 that any of the nine products that you're giving
8 testimony about today have failed in vivo?

9 MR. BOWMAN: Object to form.

10 THE WITNESS: I mean, that's why
11 there's a lawsuit because there's an injury because
12 of the device. So, I mean, I'm not focusing on the
13 clinical aspects of that. I -- I guess I really
14 don't understand what you're asking me.

15 BY MR. HUTCHINSON:

16 Q. Are you aware of any evidence that a
17 patient's mesh, from any of the nine products --

18 A. Yeah.

19 Q. -- failed to do what it was intended to
20 do?

21 A. I mean, I know there are clinical
22 studies that have looked at this, but I just -- I
23 don't -- I mean, I have to look at -- I can't
24 remember -- I mean this wasn't what I was focusing

1 on in the report, right? It was more what happens
2 to polypropylene. So there are studies that -- you
3 know, I mean, the Clavé study is these meshes --
4 you know, they were explanted because they failed
5 so. . .

6 Q. Can you tell us the name of a patient
7 whose product did not work as intended?

8 A. I mean, I didn't even -- I didn't look
9 at patient records. I'm not a medical doctor.
10 My -- my -- my report was focused on what happens
11 to polypropylene that's implanted in the body and
12 if there are --

13 Q. And you can't tell us the name of
14 somebody whose product has failed once it's in the
15 body, correct?

16 A. Well, I mean, I know that there's a --
17 you know, the Huskey case, the Edwards case. I
18 mean, these patients had complications associated
19 with the mesh. So those are -- those are the cases
20 that I have worked on.

21 Q. Doctor, let's talk about
22 biocompatibility.

23 A. Okay.

24 Q. You'll agree that Ethicon performed

1 biocompatibility testing for the PROLENE --

2 A. If you could be a little more specific.
3 You mean ISO 10993 testing?

4 Q. (Indicating yes.)

5 A. Yeah. This is standard for any -- any
6 biomedical device.

7 Q. Do you have any criticisms of the
8 biocompatibility testing that Ethicon did for any
9 of the nine products?

10 A. I've not testified about the ISO 10993
11 biocompatibility testing, other than it's in my
12 report that I -- I believe they should have done
13 some of this testing with the oxidative medium, but
14 that's -- that's not necessarily part of the -- I
15 mean, there's -- there's a -- there are some tests
16 on degradation with ISO 10993, but that medium is
17 typically not used. My testimony has been that
18 they should have looked at that.

19 But I've not critiqued -- I've not
20 expressed opinions about whether that -- could you
21 repeat your question? I -- I'm sorry.

22 Q. Well, do you have any criticisms --

23 A. Criticism --

24 Q. -- of Ethicon's biocompatibility

1 testing of the PROLENE contained in any of the nine
2 products, other than the oxidative opinions that
3 you're --

4 A. I've not discussed the ISO testing in
5 my report. I've not opined on that.

6 Q. But my question is, yes or no, do you
7 have any opinions, other than the oxidative
8 opinions that you're giving, regarding the
9 biocompatibility testing of any of the nine
10 products?

11 A. No. It's not in my report. I've not
12 discussed it.

13 Q. You stated earlier that you have
14 inspected mesh explants with Dr. Dunn.

15 A. I've seen mesh -- mesh explants with
16 Dr. Dunn and Dr. Iakovlev.

17 Q. What products were those explants from?

18 A. I believe it was an AMS mesh. I don't
19 remember the -- it was -- I think it was POP, but I
20 can't remember the exact device name.

21 Q. AMS, American Medical Systems?

22 A. That's right.

23 Q. Have you ever inspected a PROLENE mesh
24 explant from any of the nine products that we're

1 here today about?

2 MR. BOWMAN: Objection. Asked and
3 answered.

4 THE WITNESS: I've seen -- I -- in
5 visiting Dr. Iakovlev with plaintiff's counsel a
6 few years ago, I looked at a number of mesh. I
7 don't remember him identifying any of those as
8 PROLENE, but I've -- I've -- I've seen those
9 explanted meshes.

10 BY MR. HUTCHINSON:

11 Q. But you've never seen an explanted
12 PROLENE mesh from any of the nine products,
13 correct?

14 A. Perhaps. I just -- I -- I don't know
15 if it was PROLENE or not.

16 Q. You can't tell us about it, sitting
17 here today; is that right?

18 A. No.

19 Q. And you've never done any testing of a
20 PROLENE mesh explant from any of the nine products,
21 correct?

22 A. Not from these nine products. Right.

23 Q. Doctor, going to these nine products,
24 have you ever seen these?

1 A. Seen these specific products?

2 Q. Yes, sir.

3 A. I've seen, I believe, the TVT, the
4 TVT-O, the TVT-S, the ABBREVO because of previous
5 litigation. The POP kits, I can't remember.

6 Q. Have you ever seen TVT EXACT?

7 A. I don't remember.

8 Q. You don't remember if you've ever seen
9 PROSIMA, GYNEMESH PS, PROLIFT or PROLIFT+M?

10 A. Not those specific -- I mean, I've seen
11 POP devices, but I -- I -- I can't remember, you
12 know, who exactly they were manufactured by.

13 Q. Have you ever held any of these
14 products, these nine different products in your
15 hand?

16 A. Well, I mean, the -- the slings, the
17 TVT, yeah. I've seen them and. . .

18 Q. I'm sorry?

19 A. Yeah, I mean, I've held them, stretched
20 them, you know, these kinds of things.

21 Q. Where?

22 A. With Dr. Dunn at Vanderbilt. I mean,
23 the testing that he did, right? So --

24 Q. Does Dr. Dunn still has these exemplars

1 that you handled --

2 A. I don't know. I'm sorry. I don't
3 know. I don't know what he has right now.

4 Q. But you've never retained a PROLENE
5 exemplar, have you?

6 A. I have not.

7 Q. Do you know how long any of these nine
8 products have been on the market?

9 A. Well, the TVT has been out for a while,
10 since the '90s. I -- I don't remember the exact
11 dates they were introduced. But the TVT was the
12 first.

13 Q. Do you know the physical dimensions of
14 any of these products?

15 A. No. No, I don't.

16 Q. Do you know how many newtons of force
17 are placed on the mesh from any of these nine
18 products once -- once they're implanted in vivo?

19 MR. BOWMAN: Object to form.

20 THE WITNESS: There are some studies
21 that have looked at that. I don't -- I didn't
22 really discuss that in this report. So I don't
23 remember what those forces are. But there have
24 been some studies that looked at the force on a

1 sling. And I'm familiar with some of those
2 studies.

3 BY MR. HUTCHINSON:

4 Q. Do you -- do you know -- well, do you
5 have any opinions -- strike that.

6 You're not an expert in the
7 manufacturing process of PROLENE, pelvic mesh, are
8 you?

9 A. Manufacturing PROLENE? I'm -- I'm not
10 expressing opinions about the specific
11 manufacturing process.

12 Q. Are these meshes -- are they woven or
13 are they knitted for the nine different products?

14 A. For the nine products?

15 MR. BOWMAN: Object to form.

16 THE WITNESS: Could you explain what
17 you mean by woven versus knitted? That's kind of
18 a --

19 BY MR. HUTCHINSON:

20 Q. Getting deep?

21 A. I mean, what do you mean by "woven"? I
22 mean, is it like --

23 Q. Can you answer the question as it's
24 phrased?

1 MR. BOWMAN: Object to form.

2 THE WITNESS: I'd have to refresh
3 myself with the documents. I -- I -- I can't
4 remember them.

5 BY MR. HUTCHINSON:

6 Q. And as a material scientist, you'll
7 agree that PROLENE has a different chemical
8 composition than pure polypropylene, correct?

9 A. So PROLENE has two antioxidants, one
10 designed to prevent oxidation during
11 high-temperature processing, another during
12 storage. There are flow additives designed to make
13 extrusion easier, calcium stearate, some
14 surfactants. So there's other additives in there,
15 but those additives are added mainly for
16 manufacturing, in my understanding.

17 Q. Right. But PROLENE has a chemical
18 different composition -- strike that.

19 PROLENE has a different chemical
20 composition than pure PROLENE, correct?

21 MR. BOWMAN: Object to form.

22 BY MR. HUTCHINSON:

23 Q. I'm sorry. PROLENE has a different
24 chemical composition than pure polypropylene,

1 correct?

2 A. Well, the -- yeah, the composition's
3 different because it has these additives.

4 MR. HUTCHINSON: I'm sorry. Did he say
5 "well, yeah"?

6 (Whereupon the previously mentioned
7 answer was read back by the reporter.)

8 THE WITNESS: I probably said -- yes,
9 it's -- it has additives.

10 BY MR. HUTCHINSON:

11 Q. Doctor, turn to Exhibit 1. I'll
12 represent to you and the Court that there are 44
13 different plaintiffs named on the notice of
14 deposition, starting with Marty Babcock --

15 A. Okay.

16 Q. -- and ending with Thelma Wright.
17 That's 44 different cases.

18 A. I see.

19 Q. Did you know you were designated in 44
20 cases in this litigation?

21 A. I -- I didn't know the exact number of
22 44. I knew it was a wave. So I knew there were a
23 number of cases, but I wasn't familiar with the
24 specific plaintiffs because I'm not giving

1 plaintiff-specific opinions.

2 Q. Do you know what products any of these
3 44 different women received?

4 A. No. As I said, I didn't review the
5 medical records. I'm -- I'm discussing -- my
6 opinions are all related to PROLENE and
7 polypropylene in -- in the body. Yes.

8 Q. And you don't know any of the implant
9 or explant dates for any of these women, correct?

10 A. I don't. I haven't reviewed that.

11 Q. And do you know the reason why any of
12 these women had their mesh removed?

13 A. Again, it's not -- I haven't reviewed
14 their clinical records, medical records, so I
15 wouldn't know.

16 Q. Do you even -- do you even know if any
17 of these women had their mesh removed?

18 A. I know that some of them do because I
19 know that some of these cases have specimens for
20 pathology. I know Dr. Iakovlev and Dr. Timms have
21 looked at that. So some of the patients have
22 explants. Some don't.

23 Q. Do you know who has an explant and who
24 does not?

1 A. No. Again, I didn't review the medical
2 records.

3 Q. Doctor, do you think it would have been
4 helpful for you to have reviewed or inspected a
5 plaintiff's explant in this litigation?

6 MR. BOWMAN: Object to form.

7 THE WITNESS: I mean, again,
8 Dr. Iakovlev is providing those patient-specific
9 opinions. My opinions are -- I mean, it would have
10 been helpful, but it's a lot of cases. It's a lot
11 of explants. It's a lot going on.

12 BY MR. HUTCHINSON:

13 Q. Right. But you wish you would have at
14 least had the opportunity to have reviewed an
15 implant -- I mean, I'm sorry -- an explant,
16 correct?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: It would have been
19 helpful, but not realistic. I mean, it's just --

20 BY MR. HUTCHINSON:

21 Q. Why wouldn't it have been realistic?

22 A. Well, there's -- there's just a lot of
23 plaintiffs. There's a lot of patients. There's a
24 lot of explants and there's other experts that are

1 working with those explants. So they have to be
2 managed in a -- in a way that's appropriate. And
3 if Dr. Iakovlev needs explants to do the microscopy
4 then -- for a patient-specific opinion, then he
5 needs to have priority to look at that explant.

6 Q. And, Doctor, have you ever asked to
7 inspect any of the explants available from these
8 women?

9 A. I've not asked in a specific case.

10 Q. Why not?

11 A. Again, there just isn't time. I mean,
12 it's -- it's not a realistic request.

13 Q. Doctor, if you were giving an opinion
14 about a specific product, would you not want to
15 have all the evidence available to you before
16 giving that opinion?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: Again, I wasn't giving a
19 patient-specific opinion. I was giving an opinion
20 about what happens to polypropylene when it's
21 implanted in the body. That's -- so --

22 BY MR. HUTCHINSON:

23 Q. I understand. But are you going to
24 tell the jury that Marty Babcock's mesh oxidized

1 when it was in her body?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: I didn't specifically
4 look for oxidation in her mesh. What I've been
5 telling the jury is that my opinion is that
6 there's -- there's a significant risk of this
7 happening. It's a -- that's been the body of my
8 opinions and my testimony. But I'm not giving a
9 patient-specific opinion about Ms. Babcock. I -- I
10 didn't look at that.

11 BY MR. HUTCHINSON:

12 Q. Then, Doctor, are you -- did you
13 specifically look for oxidation for any of these
14 women listed on Exhibit 1, the notice of
15 deposition?

16 A. No. My understanding is that
17 Dr. Iakovlev is -- is doing that explant work. And
18 so this is -- this is an effort where there's lots
19 of experts involved. And Dr. Iakovlev is giving
20 those patient-specific opinions.

21 Q. Doctor, is it fair to say that you've
22 never done any analytical testing of explants of
23 PROLENE mesh?

24 A. I mean, I think you asked this before.

1 Not PROLENE, but the AMS mesh.

2 Q. And you've never done any physical
3 property testing of PROLENE explants, have you?

4 A. Not for PROLENE.

5 Q. And not of pristine PROLENE, have you?

6 A. Well, again, the work that I referred
7 to earlier with Dr. Dunn, I believe there were some
8 Ethicon meshes in those measurements of molecular
9 weight, but it's been a long time and we haven't
10 been relying on that. But -- but we did something
11 like that a couple years ago.

12 Q. Doctor, you've never done any tests to
13 confirm oxidation of the mesh contained in any of
14 these women listed on the notice of deposition,
15 correct?

16 A. Again, I -- I thought I answered that,
17 too. Dr. Iakovlev is doing that. I'm not giving
18 those patient-specific opinions.

19 Q. And, Doctor, can you make any
20 prediction about when the mesh, from any of these
21 44 women, would oxidate in vivo?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: Again, I -- my testimony
24 has been that it's -- it's a risk. There's a lot

1 of factors that affect it and in what patient and
2 at what time. It's not -- that's the problem is
3 you -- you -- you can't predict it. I mean,
4 that's -- that's the problem is it's unpredictable.

5 BY MR. HUTCHINSON:

6 Q. In fact, you can't make any type of
7 prediction of when Marty Babcock's mesh oxidized in
8 her body, can you?

9 MR. BOWMAN: Object to form.

10 THE WITNESS: That's not in my opinions
11 in my report. My report is that this is a risk.
12 This -- this happens. And it depends on, you know,
13 it's -- it's a risk. You can't predict when it's
14 going to happen. You can't design around it.
15 That's my opinion. It's not -- I didn't write an
16 opinion specific to Ms. Babcock when it's going to
17 oxidize or did it. I. . .

18 BY MR. HUTCHINSON:

19 Q. And you can't even sit here today
20 telling us whether or not Marty Babcock's mesh
21 oxidized in the body, can you?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: I believe it's oxidizing.
24 That's the chemical reaction. But the implications

1 of that are difficult to predict.

2 BY MR. HUTCHINSON:

3 Q. But my question is, sir, are you
4 testifying, to a reasonable degree of scientific
5 certainty, without having reviewed an explant, that
6 Marty Babcock's mesh is oxidizing in her body?

7 MR. BOWMAN: Object to form.

8 THE WITNESS: I mean, I believe that
9 the science tells you it's oxidizing. I did not
10 specifically measure it.

11 BY MR. HUTCHINSON:

12 Q. Thank you. In fact, you didn't
13 specifically measure oxidation of any of the women
14 listed in Exhibit Number 1, correct?

15 A. I've already answered that. No.

16 Q. Okay.

17 A. Yeah, I didn't do that.

18 Q. And you can't tell us whether or not
19 the mesh of any of the women listed in Exhibit 1
20 oxidized in their body, can you?

21 MR. BOWMAN: Object to the form. Asked
22 and answered.

23 THE WITNESS: I believe I've asked --
24 I've answered this. I mean, it's -- the science

1 tells you that that would be -- you would expect it
2 to oxidize and degrade. The -- the timing of that
3 is unpredictable. That's what I've said. I didn't
4 measure it. But scientific evidence --
5 polypropylene oxidizes. There are cells in the
6 body that make reactive oxygen species, and you
7 would expect it to oxidize in the body based on
8 the -- what we know scientifically.

9 BY MR. HUTCHINSON:

10 Q. I understand that. But I'm -- my
11 question is related to these 44 women. Can you
12 tell us, to a reasonable degree of scientific
13 certainty, whether or not the mesh, in any of these
14 44 women, ever oxidized?

15 MR. BOWMAN: Object to form. This is
16 asked and answered.

17 THE WITNESS: I feel like we're going
18 to go round and round on this.

19 (Simultaneous speaking.)

20 MR. BOWMAN: I'm going to instruct him
21 not to answer.

22 (Reporter interruption for
23 clarification.)

24 MR. BOWMAN: I said if we're going to

1 keep asking the same question, I'm going to start
2 instructing him not to answer.

3 BY MR. HUTCHINSON:

4 Q. I need a clean answer, then I'll move
5 on.

6 MR. BOWMAN: Objection.

7 THE WITNESS: I'm giving you my clean
8 answer. I've said this in trials. I've said this
9 in depositions. You know the record of my
10 testimony. It hasn't changed.

11 The scientific principles states that
12 this chemical reaction is going to occur. It's
13 going to oxidize. The clinical implications of
14 that are unknown. I did not specifically look at
15 oxidation in these meshes. My testimony has been
16 that these reactions are occurring. And the
17 clinical implication of that in a specific patient
18 is unknown. It's unpredictable. That's been my
19 testimony. I --

20 BY MR. HUTCHINSON:

21 Q. And you can't tell us when it's
22 occurring, can you, in any of these 44 women?

23 A. I think that's what unpredictable means
24 is you don't -- you don't know when it's -- when it

1 could happen, when it -- when it happens. You
2 don't -- you don't know when that's going to occur.

3 Q. Doctor, can you tell us the name of a
4 patient who has had their mesh removed specifically
5 because of oxidations?

6 A. I mean, in the papers, the patient
7 names aren't provided. It's a violation of
8 confidentiality rules. I mean, in the --

9 Q. Okay. Then let's not --

10 A. In a specific case.

11 Q. Okay. Then let's not look --

12 A. I mean, all these case --

13 Q. Let's look at the -- let's not look at
14 the papers or the literature.

15 A. I mean, I don't want to get into
16 patient names. That's kind of -- there's all these
17 cases, and this is a specific case. I mean, we've
18 looked at the plaintiffs in this specific case. I
19 don't -- I'm not comfortable discussing specific
20 patients from other litigations.

21 Q. I understand. And I'm not asking you
22 to discuss any patients from any literature or any
23 other litigation. What I'm asking about is the
24 Ethicon litigation.

1 Can you tell us the name of a patient,
2 who received any one of the nine products, who had
3 their mesh specifically removed because of
4 oxidation?

5 A. Why would you remove a mesh for
6 oxidation? You remove it for another complication.
7 I mean, it's not -- oxidation leads to
8 embrittlement and degradation. So -- I mean,
9 they're -- they're removed because they become
10 embrittled. They extrude. They cause pain. Not
11 because -- I mean, there's not -- you wouldn't --
12 I'm confused. I'm sorry. Go ahead.

13 MR. HUTCHINSON: Move to strike as
14 nonresponsive.

15 BY MR. HUTCHINSON:

16 Q. Doctor, I'm asking for a name of
17 somebody who received any one of these nine
18 products who had their mesh specifically removed
19 because of oxidation. Can you tell us a name? Yes
20 or no? And then I'll move on.

21 A. This is a strange question. You
22 wouldn't remove a mesh for oxidation. It's a very
23 early event. I mean, I don't know that any of
24 these patients had it removed for oxidation. Like

1 I said, I haven't reviewed their records. I don't
2 know why their mesh was removed.

3 Q. Okay. And you -- you don't -- you
4 can't tell us the name of one patient, of any of
5 these nine products, who had their mesh removed
6 specifically because of oxidation?

7 A. I just answered that.

8 Q. No. You told me it was a strange
9 question.

10 A. Well, it is a strange question. I
11 stick by that.

12 But meshes are removed because of
13 complications, like pain, erosion, and extrusion
14 that a clinician can see. So -- I -- I just don't
15 want to be trapped in some kind of answer, yes or
16 no, to a question like that. They --

17 Q. Well, Doctor, I'm entitled to flesh out
18 your opinions. And my question is can you tell us,
19 sitting here today, the name of a person, who
20 received any one of these nine products, who had
21 their mesh specifically removed because of
22 oxidation?

23 MR. BOWMAN: You can answer yes or no.

24 THE WITNESS: No, none of these

1 patients --

2 MR. BOWMAN: If you can.

3 THE WITNESS: To my knowledge, none of
4 them -- I don't -- I don't know that any of them --

5 BY MR. HUTCHINSON:

6 Q. I'm sorry. "To my knowledge none of
7 them" what?

8 A. I don't know -- I said I don't know why
9 the mesh was removed in these patients. So I
10 wouldn't know if it was removed to oxidation
11 [verbatim]. I don't know that any of them had it
12 removed for -- because of oxidation.

13 Q. Okay.

14 A. I don't know that.

15 Q. And you can't tell us the name of one
16 person who had their mesh removed because of
17 oxidation, can you?

18 A. Why are you --

19 MR. BOWMAN: Object to form.

20 THE WITNESS: I'm really -- I'm getting
21 a little frustrated. Can we answer this and take a
22 break? I don't want to get angry.

23 BY MR. HUTCHINSON:

24 Q. That's fine. Just answer it, and then

1 we can take a break.

2 A. The name -- the 44 names on this
3 list --

4 Q. My question to you is can you tell us
5 the name, sir, of one patient who received any one
6 of the nine products who had their mesh
7 specifically removed because of oxidation?

8 A. I've already answered that. I don't
9 know of a patient that had it removed because of
10 oxidation of these 44 patients.

11 Q. Okay. Or of any patients, not
12 necessarily the 44.

13 A. I'm going with these 44 patients
14 because it's this litigation. I don't want to
15 answer questions about other litigation.

16 Q. Okay.

17 A. I thought I made that clear. I'm
18 talking about these 44 patients.

19 Q. Okay. Thank you.

20 A. Can we take a break? I don't want to
21 get agitated.

22 MR. HUTCHINSON: That's fine.

23 (Brief recess.)

24 BY MR. HUTCHINSON:

1 Q. Dr. Guelcher, do you have any evidence
2 to confirm that any of the -- these women had
3 molecular weight loss of their explants?

4 A. You know, I didn't look at molecular
5 weight in -- as I said before, I didn't look at
6 their explants. I didn't look at their patient
7 records.

8 Q. Doctor, do you have any evidence to
9 confirm that any of these women -- and, again, I'm
10 talking about the women that you're here to give
11 testimony about today -- had explants that had a
12 change in physical properties?

13 A. No. I didn't look at patient explants,
14 so I don't know the change in physical properties.

15 Q. And, Doctor, do you have any evidence
16 to confirm that these women's explants lost any
17 antioxidants?

18 A. No. Again, that wasn't measured,
19 whether they lost antioxidants.

20 Q. And, Doctor, using solid scientific
21 data is good science, isn't it?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: That's a very vague --
24 I'm not -- I'm not sure what you mean by that

1 question.

2 BY MR. HUTCHINSON:

3 Q. All right. Doctor, have you ever
4 instructed your students at Vanderbilt to use
5 scientific data in reaching a conclusion?

6 MR. BOWMAN: Object to form.

7 THE WITNESS: Again, we do experiments,
8 make measurements and test hypotheses.

9 BY MR. HUTCHINSON:

10 Q. All right. And, Doctor, let's talk
11 about these nine specific products that you're here
12 to give testimony about.

13 Are you aware of any data that confirms
14 these nine specific products degraded to the extent
15 it compromised the functionality of the product?

16 MR. BOWMAN: Object to form.

17 THE WITNESS: Again, you've asked this
18 many times. I've not looked at physical changes in
19 these specific products, these patients. I've not
20 looked at that. I didn't test the explants.

21 BY MR. HUTCHINSON:

22 Q. I understand that. But my question is
23 a little bit more general, is -- and it relates to
24 these nine specific products, okay? Are you aware

1 of any data that confirms these nine products will
2 degrade to the extent their intended function is
3 compromised during a woman's lifetime?

4 MR. BOWMAN: Object to the form.

5 THE WITNESS: Again, you asked this
6 before and I said, no, for these products that's
7 not been directly measured.

8 BY MR. HUTCHINSON:

9 Q. And, Doctor, do you know -- we talked
10 about -- well, strike that.

11 Do you know what the mechanism of
12 action of tissue negatively reacting to any of
13 these nine products is?

14 MR. BOWMAN: Object to form.

15 THE WITNESS: Can you repeat that?

16 BY MR. HUTCHINSON:

17 Q. Right. Doctor, do you believe that the
18 tissue in women negatively reacts to any of these
19 nine products?

20 A. The --

21 Q. Or are you qualified to give that
22 opinion?

23 A. Well, I believe I'm -- that's what my
24 report is about. That's what these papers are

1 about, is that the -- the macrophage is to treat
2 reactive oxygen that degrades the polypropylene.
3 Has that been tested for these nine specific
4 products? Well, you asked about this earlier. And
5 I -- I said I don't know of any study looking at
6 these nine specific projects, but that's --

7 Q. You mean products, not projects?

8 A. Products. But that's -- but the nature
9 of the chemistry in the inflammatory reaction and
10 the nature of the material tells us that these
11 things will happen, but --

12 Q. All right. Well, Doctor, what is --

13 A. -- it's not been specifically measured,
14 for these products.

15 Q. What is the mechanism of action of how
16 tissue negatively reacts to any of these nine
17 products?

18 MR. BOWMAN: Object to form.

19 THE WITNESS: I mean -- but -- but
20 my -- my struggle is your question is very vague.
21 I mean, there's a number of tissue reactions.
22 There can be a fibrotic response, which is
23 fibroblasts migrating in and laying down a scar
24 plate, by depositing extra cellular matrix

1 resulting in a scar plate. I should be more
2 precise.

3 There's the macrophages and other
4 inflammatory cells, foreign body giant cells, that
5 migrate into the mesh, adhere to the mesh, secrete
6 reactive oxygen species, including hydroxyl
7 radicles, that oxidize the polypropylene. That --
8 that -- that's in my report. That's the -- that's
9 the tissue response. The primary components are
10 the fibroblasts and -- and with the collagen matrix
11 deposition and the -- and the macrophages.

12 BY MR. HUTCHINSON:

13 Q. Doctor, can you tell us from a
14 physiological standpoint how oxidation causes pain
15 in a woman?

16 A. Again, it's in my report. Oxidation
17 leads to reduction of molecular weight,
18 embrittlement, and that can lead to cracking, which
19 can lead to erosions and pain. It's hard plastic
20 in the pelvic floor. That's going to cause pain.

21 Q. And oxidation also leads to reduction
22 in physical properties, correct?

23 MR. BOWMAN: Objection to form.

24 THE WITNESS: What -- physical

1 properties, again, is -- is broad. I mean, it's --

2 BY MR. HUTCHINSON:

3 Q. Of the -- of the material.

4 A. It --

5 Q. Oxidation -- you talked about oxidation
6 leads to reduced molecular weight. Oxidation also
7 leads to reduced physical properties, correct?

8 A. Like what physical properties are you
9 referring to? I'd like you to be more specific. I
10 mean, it's -- it's reducing the molecular weight,
11 which leads to embrittlement. That's the science
12 of polypropylene oxidation. It's in the report.

13 I'm not sure what you mean by other
14 physical properties. It would help me if you could
15 be more specific.

16 Q. Well, oxidation, Doctor, causes a
17 reduction in tensile strength, doesn't it?

18 A. Reduction -- that's a mechanical
19 property, right? So. . .

20 Q. Well, strike that.

21 So let me be clear, and we can just
22 move on.

23 A. Okay. I'm just struggling to
24 understand your question.

1 Q. That's fine. Oxidation -- stay with
2 me. Do you need to take another break?

3 A. No. I'm fine.

4 Q. All right. Oxidation leads to a
5 reduction in mechanical properties of the mesh,
6 correct?

7 A. Yeah. It leads to changes. It leads
8 to embrittlement, which would be the material
9 becomes brittle rather than a ductile polymer.

10 Q. And a loss of molecular weight leads to
11 reduced tensile strength, doesn't it?

12 A. Yeah, I mean, it can. If you have a
13 reduction in molecular weight, it -- it depends
14 on -- reduction in molecular weight can lead to
15 reduced strength.

16 Q. Okay. And we're talking about strength
17 is how -- is how tough a polymer is; is that right?

18 A. Well, I wouldn't say -- tough is an
19 area under the stress versus strain curve, but
20 strength is the force or the -- you know, the --
21 the stress, the force per unit area required to
22 break the fiber or the mesh.

23 Q. Well, loss of molecular weight leads to
24 a decrease in toughness under the stress-strain

1 curve, doesn't it?

2 A. I mean, it can. It's -- it's -- if
3 it's -- if it becomes embrittled, it's going to
4 fail at a lower elongation or strain, and that
5 would lead to reduction in toughness.

6 Q. In fact, that's what you would expect
7 as a polymer scientist. If a polymer becomes
8 embrittled there will be a decrease in toughness
9 under the stress-strain curve, correct?

10 A. It -- generally speaking, it would, but
11 the problem is this is happening at the surface of
12 the fiber. So it's difficult to measure it. It's
13 not uniformly distributed across the diameter of
14 the fiber. So you may not be able to measure a
15 difference in strength even if the fiber is
16 cracked. It -- it just depends on other things.
17 Because strength is a bulk volume average property
18 versus what's happening at the surface.

19 Q. Sir, would a crack in a polymer
20 increase or decrease its mechanical properties?

21 A. Depends on how deep it is. If it's --
22 if it's -- if it's a penetrating -- you can have
23 crack propagation which can lead to failure of the
24 fiber.

1 Q. Doctor, would you expect a crack in a
2 polymer to ever increase the mechanical properties
3 of that polymer?

4 A. Seems unlikely.

5 Q. Thank you.

6 And, Doctor, if there was a crack in a
7 PROLENE fiber, you would expect that PROLENE fiber
8 to have reduced mechanical properties, wouldn't
9 you, sir?

10 A. As I said, it depends on the depths of
11 the crack. It depends on -- I mean, the
12 embrittlement -- these reactions all occur at the
13 surface of the fiber, and they move inwards. So
14 it -- it just depends. I mean, if the crack were
15 deep enough, it would affect the mechanical
16 properties. But it's not always going to be --
17 it's difficult to say every single time. I mean,
18 cracks generally reduce mechanical properties, but
19 it -- it's going to depend on the depth of the
20 crack and crack propagation and all that.

21 Q. I understand. And -- and -- and,
22 Doctor, you would expect a crack in a PROLENE fiber
23 to decrease the toughness of that PROLENE fiber,
24 wouldn't you?

1 A. Well, if the strain and stress to
2 break -- if the tensile strength or the elongation
3 at break --

4 (Reporter interruption for
5 clarification.)

6 THE WITNESS: Elongation at break --
7 sorry -- is reduced, then the toughness would be
8 reduced if it's the area under the stress-strain
9 curve.

10 BY MR. HUTCHINSON:

11 Q. In fact, Doctor, you're familiar with
12 the area under the stress-strain curve, aren't you?

13 A. Familiar with it?

14 Q. Yeah. You're familiar with the
15 concept --

16 A. Yes.

17 Q. -- toughness as defined --

18 A. Yeah, I've published on that. Yes.

19 Q. Yes. Okay. And that's something you
20 teach your students about; is that right?

21 A. I've taught that before.

22 Q. Doctor, when we get -- let's go -- go
23 back to antioxidants for a minute. I think you and
24 I can agree that the formulated product PROLENE has

1 antioxidants in it, correct?

2 A. It does. DLTDP -- and I don't remember
3 the name of the other one. There are two
4 different -- one is a radical scavenger. The
5 other, I think, is a sulfa compound, thio compound.
6 I can't -- thioester. I can't remember the exact
7 chemical formula.

8 (Whereupon Exhibit 5 was marked as an
9 exhibit.)

10 BY MR. HUTCHINSON:

11 Q. Doctor, I'll hand you what we'll mark
12 as Exhibit 5 to your deposition.

13 A. Okay.

14 Q. Can you draw out the chemical structure
15 of DLTDP as used in PROLENE in any of these nine
16 products?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: I don't remember the
19 chemical structure of the -- of the antioxidant.

20 BY MR. HUTCHINSON:

21 Q. Doctor, can you draw out the chemical
22 structure of Sanotox R, on that sheet of paper I've
23 handed you marked as Exhibit 5, as used in any of
24 these nine products?

1 A. I don't remember the chemical structure
2 that I could write it down.

3 Q. You could?

4 A. No. I don't remember what it exactly
5 is.

6 Q. You can't draw the chemical structures
7 on Exhibit 5 of DLTDP or Sanotox R, can you?

8 MR. BOWMAN: Object to form.

9 THE WITNESS: I mean, I haven't
10 memorized their chemical structures. I know what
11 they do and what they are, but I haven't memorized
12 their chemical structures. I don't typically do
13 that in my. . .

14 BY MR. HUTCHINSON:

15 Q. Doctor, can you show me chemically how
16 they perform in oxidation -- I'm sorry.

17 Can you show me chemically how they
18 perform as antioxidants, on that piece of paper as
19 Exhibit 5?

20 MR. BOWMAN: Object to form.

21 THE WITNESS: Again, that's a complex
22 reaction mechanism. I haven't memorized it. It's
23 in a number of books. But my understanding is it's
24 basically, you know, radical scavenger. I mean,

1 scavenging free radicles that -- that are produced
2 in this oxidation reaction. Whether they come
3 from -- I'll leave it at that.

4 BY MR. HUTCHINSON:

5 Q. Doctor, on Exhibit 5, can you draw the
6 chemical structure for PROLENE as used in any of
7 these nine products?

8 MR. BOWMAN: Object to form as to
9 "draw."

10 THE WITNESS: Again, it's a difficult
11 question. I mean, PROLENE is polypropylene with
12 some additives in it. So it's -- I don't remember
13 the exact compositions of the additives. It's in
14 the, you know, half percent to percent range. It's
15 pretty low.

16 BY MR. HUTCHINSON:

17 Q. Right. And my question, Doctor, is not
18 whether you remember, but can you draw the chemical
19 structure for PROLENE as used in any of these nine
20 products on the piece of paper I've marked as
21 Exhibit 5 to your deposition?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: But you can't draw the
24 composition of PROLENE. It's a -- it's a -- it's a

1 blend. It's a composite. It's polypropylene with
2 these other additives in it. So I'm not -- you
3 want me to draw the -- I mean, I'm not sure what
4 you want me to do.

5 BY MR. HUTCHINSON:

6 Q. I want you to draw the chemical
7 structure for PROLENE. Can you do that on Exhibit
8 5?

9 MR. BOWMAN: Object to form.

10 THE WITNESS: You can't draw the
11 chemical structure of PROLENE because it's
12 polypropylene with all these other -- other
13 additives in it. So it's not a -- it's not a
14 specific molecule. It's a formulation. It's a
15 blend. It's not --

16 BY MR. HUTCHINSON:

17 Q. Sir, do you know what the chemical
18 structure for polypropylene looks like?

19 A. Yeah. I mean, it's in my report. I
20 mean, it's --

21 Q. I mean, Doctor, where, on that chemical
22 chain, are the additives of DLTDP and Sanotox R
23 added? Can you tell us that?

24 MR. BOWMAN: Object to form.

1 THE WITNESS: I don't -- I don't think
2 that they're added to the chain. They're blended
3 in with the polymer. I don't -- I don't think
4 they're necessarily reacting with it.

5 BY MR. HUTCHINSON:

6 Q. Doctor, do you know what step in the
7 manufacturing process DLTDP or Sanotox R is added?

8 A. In the manufacturing process of
9 PROLENE?

10 Q. Yes, sir.

11 A. Could you repeat the question? I'm
12 not, again, sure what you're asking.

13 Q. Do you know what step in the
14 manufacturing process where DLTDP and Sanotox R are
15 added?

16 MR. BOWMAN: Object to form.

17 THE WITNESS: I mean, these are
18 added -- it's in my report. They're -- they're
19 added to protect PROLENE.

20 BY MR. HUTCHINSON:

21 Q. Right. We're going to get to the
22 reason in a minute. But I'm asking you what step
23 in the manufacturing process --

24 A. Well, it's --

1 Q. -- these additives are added to
2 polypropylene?

3 A. Well, I was getting there. But -- so
4 the PROLENE is manufactured as pellets that are
5 then extruded into a monofilament, and my
6 understanding is it's added to those pellets prior
7 to the extrusion step. That some of the flow
8 additives can help with flow of the melt polymer
9 during extrusion, and then the antioxidants, one of
10 them at least, is protecting it from high
11 temperature oxidation during extrusion. So that's
12 my understanding of when those additives are added.

13 Q. Doctor, have you ever done any type of
14 analysis to determine whether or not the
15 antioxidants, contained in any of these nine
16 products, have been depleted?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: I've not done that, but
19 Ethicon had done that.

20 BY MR. HUTCHINSON:

21 Q. And you had the equipment at your lab
22 at Vanderbilt to do that testing, didn't you, sir?

23 A. I could do that at Vanderbilt, but
24 it -- it -- it takes funding to do that. I don't

1 have any research grants on that. It's not what I
2 do. I mean, I -- I can't -- I -- I -- I don't have
3 funding to answer that question, so I haven't done
4 that.

5 Q. And, Doctor, can you tell us what the
6 rate is for the antioxidants allegedly depleting
7 from each of these nine products?

8 A. Again, I thought I answered that. I
9 haven't measured the degradation of the
10 antioxidants in the -- in the PROLENE other than
11 those Ethicon studies that reported loss of
12 antioxidants from oxidized polypropylene. That was
13 the study that I was relying on, my opinions, one
14 of the studies.

15 Q. And, Doctor, it's fair to say that you
16 have never tested the effect antioxidants have, in
17 vivo, on Ethicon's nine products that we're here
18 about today on?

19 MR. BOWMAN: Object to form.

20 THE WITNESS: I've not looked at the
21 antioxidant depletion in these products, in vitro
22 or in vivo.

23 BY MR. HUTCHINSON:

24 Q. Doctor, do you have any evidence, as we

1 sit here today -- or strike that.

2 Do you have any scientific data that
3 shows antioxidants from any of these nine products
4 are toxic to the adjacent tissue surrounding the
5 product?

6 A. I've not opined that they're toxic to
7 the tissue. My opinions is limited to that they
8 are being depleted during this oxidation. That was
9 my opinion in the report.

10 Q. And, Doctor, can you tell us at what
11 point in time these antioxidants are depleted?

12 A. Again, it's unpredictable. It's --
13 it's -- the oxidation reactions happen and when the
14 antioxidants are depleted, when the degradation
15 starts, all of these events are -- are
16 unpredictable. That's why -- that's part of my
17 opinion, that that's a problem, that that needs to
18 be controlled.

19 Q. Doctor, we were talking about physical
20 properties of mesh in -- just a minute ago.

21 Have you ever tested the physical
22 properties of the mesh in any of these nine
23 products, such as durability?

24 A. What do you mean by "durability"?

1 Q. The physical property of durability.

2 A. I mean --

3 MR. BOWMAN: Object to form.

4 THE WITNESS: How are you defining
5 that?

6 BY MR. HUTCHINSON:

7 Q. Sir, have you ever -- have you ever
8 heard the word "durability" before as a polymer
9 scientist?

10 A. Yeah, I've heard -- I've heard the
11 word, but it would help me if you would --

12 Q. Well, my question is --

13 A. -- tell me the definition.

14 Q. -- using your definition, have you ever
15 tested the durability of the mesh of any of these
16 nine products?

17 A. I mean, I --

18 MR. BOWMAN: And I just want to stress
19 right here this is asked and answered. He already
20 testified that he hasn't tested any exemplar meshes
21 or anything about this -- that was before the last
22 break. I just want to keep moving. We've only got
23 about an hour left. I mean, I don't want to spend
24 20 minutes on this if we can help it. But that's

1 my opinion.

2 BY MR. HUTCHINSON:

3 Q. Doctor, durability, tensile strength,
4 elongation, toughness, Young's modulus, have you
5 ever studied those physical properties of the mesh
6 in any of these nine products?

7 A. No. As I've said, I've not tested
8 these meshes, these nine meshes, these nine
9 products, other than the work we did with the TVT
10 on the molecular weight analysis and the IR with
11 Dr. Dunn. That's what we did.

12 Q. But, Doctor, have you done any tests,
13 tests, on any of these nine products that can be
14 repeated and confirmed?

15 A. Well, I just answered your question, I
16 thought. We did FTIR, and we did the molecular
17 weight analysis, I believe, on the TVT a couple
18 years ago.

19 Q. And you're talking about --

20 A. It was one of Dr. Dunn's earlier
21 reports.

22 Q. Right. But you're talking about the
23 FTIR analysis --

24 A. No, I'm not talking about that. I'm

1 talking about exemplars. I'm talking about --
2 well, okay. So this study, too, we -- we did the
3 FTIR and the SEM and --

4 Q. But you're deferring to Dr. Dunn on the
5 FTIR and SEM for that -- for the study marked as
6 Exhibit 3, aren't you?

7 A. For the details of the experiments?

8 Q. Correct.

9 A. Yeah. We talked about that already.
10 Multiple times.

11 MR. BOWMAN: If can I just clear
12 something up for you.

13 MR. HUTCHINSON: (Indicating.)

14 MR. BOWMAN: There was some molecular
15 weight testing done for an AMS report that was like
16 2013 or 2014. And that got into -- they got into
17 that in the very first deposition that he had
18 taken. I can produce it to you, whatever you like,
19 but all that stuff's already been turned over and
20 discussed is my understanding.

21 MR. HUTCHINSON: Okay.

22 BY MR. HUTCHINSON:

23 Q. And I may have asked this already. But
24 chain scission lowers molecular weight, doesn't it?

1 A. Yes.

2 Q. And forgive me -- and chain scission
3 also produces carbonyl bands, correct?

4 A. It's in the report, that -- that --
5 hydrox- -- hydroperoxide and carbonyl groups result
6 in the chain --

7 (Reporter interruption for
8 clarification.)

9 THE WITNESS: Yeah. So it's in the
10 report that -- that -- I'll just keep it simple.
11 The carbonyl groups are part of the oxidation
12 process.

13 BY MR. HUTCHINSON:

14 Q. Right. But you've never seen a
15 carbonyl band on an FTIR from any of the nine
16 products after it's been implanted in vivo, have
17 you?

18 A. After it's been implanted in vivo, I've
19 not -- as I said, I've not tested explant on those
20 nine products. So I have not done that.

21 Q. Doctor, you'll -- you -- when you were
22 preparing for this litigation, you understood that
23 PROLENE is what sutures are made out of, correct?

24 A. Some sutures. I mean, PROLENE is a --

1 is the trademark name that Ethicon has given to its
2 polypropylene --

3 Q. Right. And do you know how long --

4 A. -- formulation.

5 Q. And do you know how long Ethicon
6 sutures have been on the market?

7 A. Since the '60s.

8 Q. Do you have any criticisms of Ethicon
9 sutures?

10 MR. BOWMAN: Object to form.

11 THE WITNESS: Criticisms? That's -- I
12 mean, this report is about mesh. It's not about
13 sutures.

14 BY MR. HUTCHINSON:

15 Q. Okay. But your report is also about
16 PROLENE, correct?

17 A. Yes. There's PROLENE --

18 Q. And sutures are made out of PROLENE,
19 aren't they?

20 A. They can be. Some sutures are made out
21 of PROLENE.

22 Q. And do you have any criticisms of
23 sutures made out of PROLENE, as you sit here today?

24 MR. BOWMAN: Object to form.

1 THE WITNESS: I mean, PROLENE sutures
2 are also made of polypropylene. I would believe
3 they will oxidize and degrade as well. So I think
4 that tells us something about what the mesh will
5 do. But I'm not opining about the effects of
6 sutures and the failure of sutures or -- I'm --
7 I'm -- the report's about pelvic mesh --

8 BY MR. HUTCHINSON:

9 Q. I understand that.

10 A. -- made of PROLENE.

11 Q. And you're --

12 A. I'm not clear what you're asking me.
13 I'm sorry.

14 Q. You're opining about the failure of
15 PROLENE mesh, aren't you?

16 A. Yeah. I mean, I -- yes.

17 Q. All right. Do you -- do you have
18 any -- do you have any criticisms of Ethicon's
19 PROLENE sutures, is my question?

20 A. I think I'm hung up on the word
21 "criticisms." Could you --

22 Q. Well, Doctor, are you --

23 A. -- could you be a little more --

24 Q. I cannot.

1 A. Okay.

2 Q. All right. I cannot.

3 Do you have any criticisms -- that word
4 speaks for itself -- of Ethicon's PROLENE sutures?

5 A. But "criticisms" is a broad word. I --
6 I believe that PROLENE sutures oxidize and degrade
7 just like the mesh but --

8 Q. Have you -- well, what --

9 A. Can I finish my answer, please?

10 Q. Yes.

11 A. I'm hoping my answer will make it go
12 away. But -- the -- it's implanted in a different
13 part of the body. It's -- it's a suture. It's not
14 a wo- -- you know, a multi -- it's not a -- it's
15 not a mesh. It's a suture. And so the
16 inflammatory response could be different. Location
17 in the body is different. The -- the chemical
18 reactions are going to be the same.

19 Q. Okay.

20 A. But the clinical implications are
21 different. And I'm not opining about the clinical
22 implications of oxidation and degradation on
23 PROLENE sutures used -- single fiber monofilaments
24 used as sutures. Is that --

1 Q. I understand. I understand that,
2 Doctor.

3 A. I'm really struggling here.

4 Q. But is your opinion -- is it your
5 opinion that every person who has ever had a
6 PROLENE suture has oxidized material in their body?

7 MR. BOWMAN: Object to form.

8 THE WITNESS: I believe that PROLENE is
9 made from polypropylene. It will oxidize in the
10 body. The chemistry, the biology of the
11 inflammatory response tells us these reactions are
12 going on. It's the clinical implications of those
13 reactions that are different. And I'm not speaking
14 about that with regard to sutures. It's about with
15 regard to the mesh.

16 BY MR. HUTCHINSON:

17 Q. I understand that, Doctor. But my
18 question is, is it your opinion that every person
19 who has a PROLENE suture has oxidized material in
20 their body?

21 MR. BOWMAN: Object to form. Asked and
22 answered.

23 THE WITNESS: I believe that I answered
24 it. The material --

1 BY MR. HUTCHINSON:

2 Q. Respectfully, you haven't.

3 A. I have.

4 Q. My question is about PROLENE sutures.

5 MR. BOWMAN: He did -- he did just
6 answer that question.

7 THE WITNESS: I just answered that.
8 PROLENE sutures are made out of polypropylene, and
9 they will be subject to the same oxidation
10 reactions as -- how much oxidized compared to mesh,
11 I don't know. I'm not talking about that. But
12 it's implanted at a different point in the body.
13 It's a single fiber instead of a woven mesh. But
14 it's -- because it's polypropylene, I believe it
15 still will oxidize. It's just the extent of those
16 reactions may be very different because the
17 inflammatory response may be different. I --

18 BY MR. HUTCHINSON:

19 Q. Have you investigated why there's been
20 a long-term effective use of PROLENE sutures in the
21 body?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: Can you repeat it,
24 please. I'm -- could you repeat the question?

1 BY MR. HUTCHINSON:

2 Q. Have you investigated why there's been
3 a long-term effective use of PROLENE sutures in the
4 body?

5 MR. BOWMAN: Object to form.

6 THE WITNESS: I don't know how to
7 answer that. I've looked at PROLENE sutures.
8 There are papers that I've cited. There's Ethicon
9 studies about PROLENE sutures that I've looked at.
10 And I believe those studies point to evidence of
11 oxidation and degradation like I've been
12 testifying.

13 But the -- the effects of the oxidation
14 of a PROLENE suture are going to be different than
15 for a PROLENE mesh. It's implanted in a different
16 part of the body. It's a different type of device.
17 So I don't think you can necessarily infer that the
18 safety record with PROLENE sutures translates to
19 the mesh.

20 (Whereupon Exhibit 6 was marked as an
21 exhibit.)

22 BY MR. HUTCHINSON:

23 Q. Handing you what we'll mark as Exhibit
24 6 to your deposition. And by the way, before we

1 move on, Exhibit 5 remains blank, does it not?

2 A. I didn't write anything on Exhibit 5.

3 Q. This is the -- Exhibit 6 is the Imel
4 article that you cite --

5 A. Okay.

6 Q. -- in your report. You've seen this,
7 Doctor, correct?

8 A. Yes.

9 Q. And the first paragraph, first sentence
10 says, "Polypropylene has been used as a mesh for
11 hernia repairs since 1958."

12 My question, sir, is do you have any
13 criticisms of Ethicon's hernia mesh?

14 A. My -- my opinions about hernia mesh are
15 similar to the sutures. It's implanted in a
16 different part of the body. Because it's made from
17 polypropylene, it will be subjected to these same
18 reactions. But because it's in a different part of
19 the body, the clinical implications are different,
20 and that's not the subject of my report, what
21 happens to a hernia mesh if it's oxidized and
22 degraded. That's not --

23 Q. Sir, is it your testimony that every
24 person has -- that has a hernia PROLENE mesh

1 implanted in their body has oxidized material in
2 their body?

3 A. Again, I would say how I answered that
4 before, that these reactions are ongoing. It's
5 reasonable to expect that that material would be
6 oxidized. It's just the extent and the clinical
7 implications of that are very different because
8 it's in a different part of the body.

9 Q. Okay. So if I -- I'm just trying to
10 understand your answer. But it's your testimony
11 that every person that has a PROLENE hernia mesh
12 has oxidized material in their body; it's just to
13 what extent; is that a fair summary?

14 A. To what extent? I would -- I would say
15 that --

16 Q. No. My -- I'm asking is that a fair
17 summary of your testimony?

18 A. Could you say it again?

19 Q. I did it so good the first time.

20 A. Perhaps. But I want to be very clear
21 about what I'm saying.

22 Q. Let's be clear. Is it your testimony
23 that every person who has a PROLENE hernia mesh has
24 oxidized material in their body; it's just a matter

1 of to what extent that oxidation has occurred,
2 correct?

3 A. I want to be very clear about this.
4 I -- the science -- the science tells us that
5 this -- you would expect this material to oxidize.
6 I've not measured it, but I believe the science
7 tells us that will happen. And to what extent is
8 going to depend on other factors. I -- I -- it's
9 possible -- I can't predict it. It's
10 unpredictable, the extent of the oxidation and the
11 clinical significance. But I believe that the
12 chemistry, to a reasonable degree of scientific
13 certainty, tells us that these materials will
14 oxidize when implanted in the body.

15 Q. And every person that has a hernia mesh
16 that's made out of PROLENE has oxidized material in
17 their body; it's just a -- it's just a matter of to
18 what degree; is that fair?

19 A. I mean, when exactly these reactions
20 start is not exactly clear, so there is some time
21 that it takes to happen. But, you know, I believe
22 these materials will oxidize. It's just --

23 Q. How long does it take to happen?

24 A. It's unpredictable. It depends on the

1 anatomic site. It depends possibly on the patient.
2 It depends on lots of factors, but it's something
3 that you can't predict, and it's something you
4 can't design for.

5 Q. If we look at Exhibit 6 to your
6 deposition --

7 A. Okay.

8 Q. -- none of the specimens that Imel,
9 I-m-e-l, studied were PROLENE, were they?

10 A. These were Boston Scientific meshes, so
11 they -- they did not include PROLENE.

12 Q. And when a medical device is first
13 implanted in the body, it comes in contact with
14 body fluids, fair to say?

15 A. Yes.

16 Q. And macrophages are some of those body
17 fluids.

18 A. Well, macrophage is a cell, not a
19 fluid.

20 Q. Okay. Or -- or body -- body material.
21 And macrophages contain proteins, correct?

22 A. Well, I mean, all cells contain
23 proteins, but it's a -- it's a cell. I mean, a
24 cell --

1 Q. But -- but we can agree that proteins
2 adsorb to the surface of the medical implant,
3 correct?

4 A. Well, the -- the proteins adsorb to
5 facilitate cell attachment. I mean, that the
6 adsorbed proteins facilitate --

7 Q. And --

8 A. -- the attachment to cells.

9 Q. And that occurs -- and that reaction
10 occurs within seconds of the implant; is that
11 right?

12 A. Proteins adsorb very -- fast, yeah.

13 Q. Can proteins be removed manually from
14 the explant?

15 MR. BOWMAN: Object to form.

16 BY MR. HUTCHINSON:

17 Q. Once it's taken out of the body?

18 A. Manually? What do you mean by
19 "manually"?

20 Q. Can they be scrubbed off? Can they be
21 removed with tweezers?

22 A. I mean, tissue can.

23 Q. But the protein, sir, is my question.

24 A. The adsorbed proteins? I mean, this

1 protein can --

2 Q. That's with a D.

3 A. With a D. Yeah. Sorry.

4 Can the adsorbed proteins be removed
5 mechanically? Is that what you mean?

6 Q. Yes, sir.

7 A. Probably not. It's --

8 Q. It -- it would be a chemical -- it
9 would have to be a chemical reaction or a chemical
10 protocol to remove the proteins; is that right?

11 A. Typically, you would -- you could
12 desorb them, you could break them with a
13 proteinase. Yeah. Something not mechanical.

14 Q. Okay. And, Doctor, do you know how to
15 remove proteins from a medical device after it's
16 taken out of the body?

17 A. Well, in my work, we're more concerned
18 with removing cells. So we'll use different
19 enzymes and -- and materials to remove the cells
20 from the material.

21 Q. Do you know how to clean and remove
22 proteins from an explanted piece of mesh, from a
23 chemical standpoint?

24 A. I thought I answered it; but, I mean, I

1 know Dr. Timms used proteinase. A lot of people
2 are using --

3 Q. I know what they do.

4 A. Yeah.

5 Q. But I'm asking what you know.

6 A. Well, I haven't specifically --

7 Q. Okay.

8 A. -- done that. Like I said, I'm
9 typically removing cells. But you still have to
10 digest the matrix. So we add these types of --
11 because the cells are embedded in some matrix, and
12 if you want the cells, you have to digest the
13 matrix.

14 Q. And, Doctor, you'll agree that an
15 increased layer of proteins can build up on a
16 foreign body object over time?

17 A. Yeah, protein adsorption is typically
18 going to reach some equilibrium. Now --

19 Q. But it will build up over time. The
20 proteins will build up on a medical device over
21 time?

22 A. I would like to be a little more
23 specific in my answer, if I could. The -- the
24 proteins will adsorb which can facilitate cell

1 attachment and cells can deposit matrix and that
2 combined -- it's a very complex event. It's not --
3 it's not a -- you know, I -- I guess -- I don't
4 know that -- I mean, my understanding of protein
5 adsorption is, if you're going to reach some
6 equilibrium, there's going to be some competitive
7 adsorption with different proteins. But the
8 over-time part, to me, would be more matrix
9 deposition by the cells.

10 Q. On page 1 of Exhibit 6 --

11 A. Okay.

12 Q. -- we talked about polypropylene being
13 used as a mesh for hernia repairs since the 1950s.

14 Doctor, does the pelvic region have
15 more reactive oxygen species than the abdomen? Or
16 do you know?

17 MR. BOWMAN: Object to form.

18 THE WITNESS: There have been some --
19 there's -- I know there's one paper that's been
20 published about the increased prevalence of the --
21 of ROS, things like peroxides in the vaginal space.

22 BY MR. HUTCHINSON:

23 Q. But can you quantify reactive oxygen
24 species found in the pelvic region?

1 A. I've -- I mean, I've not done that, but
2 I believe this paper -- I would have to review the
3 paper to see exactly what -- but I believe it has
4 been looked at.

5 Q. What's the name of the paper?

6 A. I just can't remember right now.

7 Q. Is it cited in your report that we've
8 marked as Exhibit 2 to your deposition?

9 A. It's probably on the reliance list. I
10 would have to check. I just don't remember. I
11 wasn't -- yeah.

12 Q. Doctor, sitting here today, can you
13 quantify -- without looking at your literature, can
14 you quantify the reactive oxygen species found in
15 the pelvic region?

16 A. I've not done that.

17 Q. Doctor, can you tell us the amount of
18 peroxides that are secreted in vivo?

19 A. Well, it's not just peroxides. It's
20 hydroxyl radicles, hypochlorous acid. There's a
21 lot of these reactive oxygen species that are
22 secreted by different types of cells.

23 Q. Okay. Well, let's take -- let's take
24 one by one. Can you tell us the amount of

1 peroxides that are secreted in vivo?

2 A. Well, maybe we can make this a little
3 faster by -- all of these reactive oxygen
4 species -- how much is secreted by adherent cells
5 on the mesh, that's not been measured, but, again,
6 it's a very localized environment. There's an
7 adherent cell on the surface and that
8 microenvironment is different from the broader
9 tissue microenvironment.

10 So it's difficult to know exactly what
11 the composition of that -- we know what's in it.
12 That's why the simulated oxidation test was
13 developed. But the exact concentrations of all
14 those species are difficult to know.

15 Q. In fact, you don't know those exact
16 concentrations of all those species sitting here
17 today, do you?

18 MR. BOWMAN: Asked and answered.

19 THE WITNESS: I mean, I thought I
20 answered it. Not for -- I mean, not -- for this
21 adherent macrophage on the surface of the
22 polypropylene, I don't -- I don't know what the
23 concentrations of all these relative species are,
24 but they're there.

1 BY MR. HUTCHINSON:

2 Q. But -- and, sir, do you have -- can you
3 give us a percentage?

4 A. I -- I -- I -- I don't know. I'd have
5 to look at some papers. I don't know the -- the
6 exact composition of that.

7 Q. And how -- how do they -- how does that
8 compare to 30 percent hydrogen peroxide?

9 A. Well, that's -- that test is -- you're
10 referring to -- okay. I'm confused. Are you
11 referring to just 30 percent hydrogen peroxide or
12 with the cobalt catalyst? I'm not -- I'm not
13 sure --

14 Q. The 20 percent. Let's use 20 percent.

15 A. Just the hydrogen peroxide?

16 Q. Uh-huh.

17 A. Well, I mean, that test was done to
18 give some estimate of what the effects could be.

19 Q. And -- and, Doctor, you'll agree that
20 20 percent hydrogen peroxide is higher than what is
21 usually seen in a clinical setting in the body?

22 A. Well, I think that's a very vaguely
23 stated -- the -- again, these -- these compositions
24 are in a -- are in a privileged microenvironment.

1 There's a pocket between the adherent macrophage
2 and the surface of the material.

3 Q. Right.

4 A. So the composition there in that
5 microenvironment is different than -- and that's
6 the concentration that matters because that's what
7 the polypropylene is exposed to.

8 Q. I understand.

9 A. So the concentration everywhere else in
10 the body doesn't really matter --

11 Q. Doctor --

12 A. -- as much.

13 Q. -- do you have any idea how much
14 hydrogen peroxide is produced by the body in a
15 foreign response -- foreign -- in a foreign body
16 response to any of these nine products that we're
17 here today on?

18 A. Again, I thought I've answered that.
19 It's this -- there's this microenvironment, and how
20 much hydrogen peroxide is in there is -- is not --
21 I don't -- I can't -- I just can't answer that
22 right now without looking at some studies.

23 Q. Okay. And, Doctor, what studies would
24 you need to look at?

1 A. I'd have to -- I just don't -- I'd have
2 to look for some papers on that. I don't -- I
3 don't -- I don't know -- I don't have it in my
4 memory what --

5 Q. Are those paper on your reliance list?

6 A. I don't know.

7 Q. Doctor, you'll agree that 20 percent
8 hydrogen peroxide is higher than what is usually
9 seen in a clinical setting?

10 A. I'm not going to agree with that. You
11 can keep asking it over and over. I'm not going to
12 agree with it. Because "clinical setting" is a
13 vague term.

14 Clinical setting, are you talking about
15 everywhere in the body or are you talking about
16 that specific microenvironment between the cell and
17 the biomaterial? I mean, it's -- it's -- it's too
18 vague of a question.

19 Q. Do you know how many micromoles of
20 hydrogen peroxide are found in the body?

21 MR. BOWMAN: Object to form.

22 THE WITNESS: Again, it's too vague of
23 a question. What's in the body -- what matters is
24 what's in that microenvironment, not what's all

1 over the body.

2 BY MR. HUTCHINSON:

3 Q. Okay. And, Doctor, can you tell us how
4 much hydrogen peroxide would be needed to oxidize
5 PROLENE in vivo?

6 MR. BOWMAN: Object to form.

7 THE WITNESS: Again, it's a question of
8 rate. The more hydrogen peroxide, other oxidative
9 species, the faster it's going to occur. What
10 exactly those concentrations are, I don't know that
11 it's been studied for polypropylene oxidation,
12 what -- what those concentrations are.

13 BY MR. HUTCHINSON:

14 Q. And I'm not asking about polypropylene
15 oxidation. I'm talking about PROLENE oxidation.
16 So let's be clear.

17 A. PROLENE's --

18 Q. Hold on just a minute. Let me finish
19 my question.

20 A. I thought you were finished.

21 Q. Doctor, can you tell us how much
22 hydrogen peroxide would cause PROLENE to oxidize in
23 vivo?

24 MR. BOWMAN: Object to form.

1 THE WITNESS: I would answer it the
2 same -- there's that microenvironment and how much
3 hydrogen peroxide is in there is -- I -- I don't
4 know. If there's some, it will oxidize. But if
5 it's going to -- it's a question of concentration.
6 The more that's there, the more it's going to
7 oxidize.

8 BY MR. HUTCHINSON:

9 Q. You can't tell us how much hypochlorous
10 acids would cause PROLENE to oxidize in the body,
11 can you?

12 MR. BOWMAN: Object to form. He's --
13 he's already made it clear that he's talking about
14 concentrations and not --

15 MR. HUTCHINSON: Understood.
16 Understood.

17 MR. BOWMAN: Okay.

18 MR. HUTCHINSON: Understood.

19 THE WITNESS: I'm just going to keep
20 saying --

21 BY MR. HUTCHINSON:

22 Q. Same question with hydrochloric acid.

23 A. So hydrochloric acid, again, it's --

24 Q. Can you tell us how much would cause

1 PROLENE to oxidize?

2 A. Well, I don't know that hydrochloric
3 acid would cause oxidation. I mean, polypropylene
4 is relatively resistant to acids and bases. It's
5 the oxidizers that it's not. So I would say that
6 all of these reactive oxygen species are -- are --
7 you know, they're present in that privileged
8 microenvironment, and they're going to cause
9 oxidation. That's what we know.

10 Q. But you can't tell us how much is
11 required to cause oxidation, can you, is my
12 question?

13 MR. BOWMAN: Object to the form.

14 THE WITNESS: I feel like I've answered
15 it. If it's there, it will cause oxidation.

16 BY MR. HUTCHINSON:

17 Q. I understand.

18 A. It's a question of the rate and the
19 extent.

20 Q. But can you tell us how -- how much
21 will cause oxidation? That's my question.

22 A. If there's some there, it will cause
23 oxidation. It's just a question of the extent. So
24 if there's more or less, there will be more or less

1 oxidation. But if the reactive oxygen species are
2 there, you would expect these reactions to be going
3 on. I guess I'm really. . .

4 Q. That's fine.

5 MR. HUTCHINSON: Move to strike as
6 nonresponsive.

7 BY MR. HUTCHINSON:

8 Q. My question to you, sir, is can you
9 tell us how much would cause PROLENE to oxidize in
10 the body?

11 A. And I believe I've answered --

12 MR. BOWMAN: Objection --

13 THE WITNESS: -- that question multiple
14 times.

15 (Simultaneous speaking.)

16 (Reporter interruption for
17 clarification.)

18 MR. BOWMAN: I have to object as
19 compound and vague. He's already made it clear
20 that he's asking -- he wants you to include
21 concentrations in -- in the amount of material
22 that's -- that's going to be oxidized, that kind of
23 thing.

24 BY MR. HUTCHINSON:

1 Q. Can you answer that question, Doctor?

2 A. I'm going to answer it the same way
3 I've been answering it. That if there is reactive
4 oxygen species in that privileged microenvironment,
5 there will be -- you would expect there to be
6 oxidation going on, and it's a question of
7 concentration. The more that's there, the more
8 oxidation you're going to get.

9 Q. And can you quantify -- and strike
10 that.

11 And can you quantify that
12 concentration?

13 MR. BOWMAN: Object to the form. Asked
14 and answered.

15 THE WITNESS: I don't know, off the top
16 of my head, by my memory, what the concentrations
17 of those reactive oxygen species are. I think you
18 asked me about that already. But I know that
19 they're there. And I -- and that -- they're there.
20 Those reactions would be expected to occur.

21 BY MR. HUTCHINSON:

22 Q. Doctor, let's go back to Sanotox R and
23 DLTDP. Do you have criticisms of Ethicon for using
24 those two specific antioxidants in their

1 formulation of PROLENE?

2 A. I believe my opinion on this matter is
3 that those antioxidants were added to protect the
4 polypropylene during the manufacturing process and
5 whether or not they're doing anything -- protecting
6 any in vivo oxidation was not looked at very much.
7 There are some studies where they show depletion of
8 oxidation in the -- depletion of antioxidants in
9 the oxidized polypropylene on the surface.

10 Q. Okay. But my question is are you
11 criticizing Ethicon for using DLTDP and Sanotox R
12 in the formulation of PROLENE?

13 MR. BOWMAN: Object to form.

14 THE WITNESS: Are you asking
15 criticizing the selection of those?

16 BY MR. HUTCHINSON:

17 Q. (Indicating yes.)

18 A. I don't know how to answer it, other
19 than I did. Those antioxidants were chosen for
20 stabilization during manufacturing and storage, not
21 for in vivo use. That's -- that's my opinion.

22 Q. So --

23 A. And they're well known to stabilize --
24 I mean, they're well known stabilizers for

1 manufacturing purposes, but not for -- necessarily
2 for in vivo oxidation.

3 Q. Doctor, but that's not my question.
4 Are you criticizing Ethicon for selecting Sanotox R
5 and DLTDP as two antioxidants used in the
6 formulation of PROLENE?

7 MR. BOWMAN: Object to form. Asked and
8 answered.

9 THE WITNESS: Again, I believe I've
10 answered it. I'm not --

11 BY MR. HUTCHINSON:

12 Q. And in all due respect -- in all due
13 respect, Doctor, you haven't. I'm just -- do you
14 criticize Ethicon? That's all my question --

15 MR. BOWMAN: He did answer that today,
16 and he's already testified about this in the Huskey
17 case. And -- but he has --

18 THE WITNESS: I'll try one more time.
19 So those two antioxidants are well known for
20 protecting polypropylene during manufacturing. I'm
21 not --

22 MR. HUTCHINSON: And move it strike as
23 nonresponsive.

24 BY MR. HUTCHINSON:

1 Q. I'm not asking you how well known they
2 are. I'm asking you if criticize Ethicon for
3 selecting --

4 A. I was trying to finish. Just let me
5 finish.

6 Q. All right. But please answer the
7 question.

8 A. Just --

9 Q. Do you criticize Ethicon for selecting
10 DLTDP and Sanotox R as antioxidants?

11 A. I'm -- I'm not criticizing them for
12 using those in the manufacturing process. I am
13 criticizing the logic that they're going to be
14 effective in vivo because that was never really
15 looked at carefully.

16 Q. Do you have a solution?

17 A. I'm not proposing a solution. I'm
18 not -- I'm not providing an opinion other than
19 that -- that that should be looked at, what -- how
20 effective are these antioxidants in vivo. That's
21 my opinion.

22 Q. And what's the alternative to these
23 antioxidants, Doctor?

24 A. Well, antioxidants are a -- are a

1 complex matter. There are many different
2 combinations that can be used. Just because a
3 certain set of antioxidants is useful for
4 protecting during manufacturing and -- and
5 long-term storage doesn't mean they'll be effective
6 in the body. That needs to be studied with in vivo
7 studies and perhaps testing different
8 concentrations, different types of antioxidants.

9 My -- my criticism has been that that
10 work has not been done, at least to a very
11 extensive degree, other than that study that showed
12 antioxidant depletion in the -- in the oxidized
13 polypropylene.

14 Q. Doctor, can you tell us the names of --
15 of the antioxidants that you believe Ethicon should
16 have used?

17 A. I believe I just answered your
18 question. I'm not -- I'm not proposing any
19 specific set of antioxidants. I'm saying that
20 studies should have been done to consider different
21 combinations, different formulations other than
22 just protecting it during the manufacturing
23 process.

24 Q. And do you have any alternatives,

1 sitting here today, to Sanotox R and DLTDP?

2 A. I'm not proposing alternatives. Those
3 two antioxidants could have been studied in vivo,
4 or they could have looked at other antioxidants.
5 There -- but -- but that wasn't done. That's --
6 that's my opinion, that I've stated many times in
7 trial and depositions and courts, and that hasn't
8 changed.

9 Q. Doctor, if we look the Imel study that
10 we've marked as Exhibit 6 --

11 A. Exhibit 6, that's -- those are -- I'm
12 sorry. You said what? Oh, Imel.

13 Q. Yeah. I-m-e-l.

14 A. I thought you said animal. Sorry.

15 Q. That's okay. Are you there with me?

16 A. I am.

17 Q. The fibers from these mesh explants
18 were not 100 percent cleaned of proteins, were
19 they?

20 A. I don't know how to answer that. In
21 this study, he found regions of oxidized
22 polypropylene that had no protein because there was
23 no nitrogen present, and he found regions where
24 there appeared to be a mix of oxidized

1 polypropylene and protein. So there were regions
2 where there were still adsorbed proteins, but there
3 are regions where there were not. That's what he
4 reports in the study.

5 Q. Okay. And, Doctor, he also reports in
6 this study a carbonyl peak at 1740; is that right?

7 A. In the IR spectra and his supplemental
8 data, he's seen a carbonyl peak at 1740 that's not
9 in the explants -- I'm sorry -- that's not in
10 the nonimplanted exemplars, but it -- it does
11 appear in the explants.

12 Q. Doctor, do you know where DLTDP has
13 a -- has a FTIR spectra showing up on the --

14 A. There's some --

15 Q. -- on the reciprocal centimeter line?

16 A. There is some internal Ethicon
17 documents that reported in that range.

18 Q. In 1740?

19 A. Uh-huh. I think so.

20 Q. Is that a "yes"?

21 A. Yes, that's what I remember.

22 Q. Okay.

23 A. There are some internal Ethicon
24 documents that show depletion, but when they took

1 those IR spectra, they blew them way up so the
2 normal -- the peaks are very small. They're
3 difficult to see.

4 Q. Doctor, have -- and I may have asked
5 you this earlier. Have you ever designed a medical
6 device product?

7 A. Have I ever designed a medical device
8 product? In my research, I work with device
9 companies on -- I have work ongoing in that area.

10 Q. And do any of the products that you
11 have worked on have a lifetime warranty?

12 A. Lifetime warranty? I mean, these are
13 degradable grafts. So they're intended to --

14 Q. The products that you're working on?

15 A. Yes.

16 Q. Okay.

17 A. So they're intended to be replaced by
18 tissue over time and go away.

19 Q. Doctor, are you aware of any medical
20 product on the market that will never oxidize?

21 A. Wow. That's a really broad question.
22 A product that will never oxidize? I don't know.

23 MR. BOWMAN: Object to form.

24 THE WITNESS: That's so vague. I. . .

1 I mean, it depends on the product and what it's
2 supposed to do, where it's implanted, what -- what
3 the expected response is.

4 MR. HUTCHINSON: Move to strike as
5 nonresponsive.

6 And this is not going to count as my
7 time. I mean, it's a very clear question.

8 BY MR. HUTCHINSON:

9 Q. My question to you is are you aware of
10 any medical device on the market that will never
11 oxidize?

12 A. This is such an extreme question. I
13 don't -- I don't know. I mean, there are -- there
14 are materials that oxidize -- that -- that oxidize
15 very slowly or not much at all that can be
16 measured, but -- I mean, there's a lot of
17 biomedical devices on the market. I haven't looked
18 at that specific question.

19 Q. Can you answer that question, Doctor,
20 sitting here today?

21 A. A device that's never oxidized? I
22 don't know. I mean, I'd have to look into that.
23 This is so broad. It's hard to answer.

24 Q. Doctor, can you tell me the name of a

1 medical device on the market that will never
2 oxidize?

3 A. And, again, it's a -- it's just a -- I
4 don't know how to answer that. That's a broad
5 question. Never oxidize. I don't -- I don't know.

6 MR. HUTCHINSON: Move to strike
7 everything before "I don't know."

8 BY MR. HUTCHINSON:

9 Q. Doctor, are you aware of any foreign
10 body material that will never oxidize in the body?

11 A. Any foreign body material?

12 Q. That will never oxidize in the body.

13 A. I don't know. Again, it's -- it's
14 extremes of oxidation. I mean, it's -- it's --
15 these are misleading questions. I don't -- I don't
16 know of any material that just doesn't oxidize.
17 I'd have to -- I don't know.

18 MR. HUTCHINSON: And move to strike
19 everything other than I don't know any material
20 that doesn't oxidize.

21 BY MR. HUTCHINSON:

22 Q. Doctor, can oxidation in pelvic mesh
23 ever be completely eliminated?

24 A. Can oxidation in pelvic mesh be

1 completely eliminated? I mean, I think it's in my
2 report. No. These -- these antioxidants --

3 Q. It's not in your report.

4 A. It is in my report.

5 Q. Listen to my question.

6 A. Okay.

7 Q. Can oxidation of pelvic mesh ever be
8 completely eliminated? That's the question.

9 MR. BOWMAN: Object to form.

10 THE WITNESS: I believe it's in my
11 report. I -- the antioxidants are depleted over
12 time. The mesh oxidizes. And the clinical
13 implications are unpredictable. You can't design
14 for it. That's my answer.

15 BY MR. HUTCHINSON:

16 Q. My -- my question is can oxidation of
17 pelvic mesh ever be completely eliminated?

18 A. I just answered it. The antioxidants
19 deplete over time, and the mesh will oxidize as
20 they're depleted, and that's going to lead to these
21 other events that are unpredictable. That's the
22 answer to the question.

23 Q. So it can be completely eliminated in
24 pelvic mesh?

1 A. I answered the question. I don't
2 really want to play this game.

3 THE WITNESS: Can I -- can we take a
4 break again? I --

5 BY MR. HUTCHINSON:

6 Q. No. I need the question answered first
7 and then we'll take a break.

8 A. We can answer it for an hour. I'm
9 going to give you the same answer I just gave you.
10 I feel like I've made these opinions very clear.

11 Q. My question is can oxidation of pelvic
12 mesh ever be completely eliminated? Yes or no?

13 MR. BOWMAN: Object to form.

14 THE WITNESS: The antioxidants are
15 depleted. As the antioxidants are depleted, you
16 expect oxidation of the polypropylene in the mesh,
17 which can lead to these other unpredictable events.

18 BY MR. HUTCHINSON:

19 Q. But can it ever be completely
20 eliminated? That is my question.

21 A. The antioxidants are --

22 MR. BOWMAN: Object to form.

23 THE WITNESS: -- depleted over time.

24 As they're depleted, the polypropylene in the mesh

1 can oxidize.

2 BY MR. HUTCHINSON:

3 Q. But can oxidation ever be completely
4 eliminated, sir?

5 A. As the antioxidants are depleted,
6 oxidation of the mesh would be expected to occur.
7 I don't know what else to say.

8 Q. My question is can it ever be
9 completely eliminated?

10 A. As the antioxidants are depleted in the
11 mesh, the polypropylene would oxidize.

12 MR. HUTCHINSON: Move to strike as
13 nonresponsive.

14 BY MR. HUTCHINSON:

15 Q. My question is --

16 MR. BOWMAN: He's actually answered
17 this question.

18 MR. HUTCHINSON: No, he hasn't. My
19 question is --

20 MR. BOWMAN: He said he wasn't giving
21 you any --

22 (Simultaneous speaking.)

23 THE WITNESS: We can sit here for --

24 (Reporter interruption for

1 clarification.)

2 THE WITNESS: We can sit here for an
3 hour if you want. I mean, it's over at 1:00.

4 As the antioxidants are depleted --

5 MR. HUTCHINSON: And move to strike as
6 nonresponsive.

7 THE WITNESS: -- the polypropylene --

8 BY MR. HUTCHINSON:

9 Q. I'm trying to be respectful to you,
10 Doctor.

11 MR. BOWMAN: No, wait a minute. I need
12 to --

13 MR. HUTCHINSON: Then we'll take a
14 break.

15 MR. BOWMAN: I need to get my objection
16 on the record. He's already said he's not offering
17 you alternatives. He's telling you what's going on
18 with the pelvic mesh that's involved here. All
19 right? Now I'm going to object as asked an
20 answered.

21 And if you want to rephrase the
22 question, go ahead.

23 MR. HUTCHINSON: All right.

24 BY MR. HUTCHINSON:

1 Q. I'm asking, Doctor, can it ever
2 be completely -- can oxidation ever be completely
3 eliminated?

4 MR. BOWMAN: I'm going to instruct you
5 not to answer.

6 THE WITNESS: I'm not going to answer.

7 BY MR. HUTCHINSON:

8 Q. Doctor, are you giving any alternatives
9 to PROLENE mesh? And your counsel said no. I just
10 want to make sure, and then we'll take a break.

11 MR. BOWMAN: Object to form.

12 BY MR. HUTCHINSON:

13 Q. Are you giving any alternatives to
14 PROLENE mesh?

15 A. I've not opined that there are
16 alternatives to PROLENE mesh. My opinions relate
17 to what happens to PROLENE implanted in the body.

18 Q. And I understand that. I know there's
19 none in your report. But are you giving, here
20 today, any opinions?

21 A. I -- I just said that. I'm not giving
22 any opinions about alternatives to PROLENE mesh.
23 I'm stating what happens to PROLENE mesh in the
24 body.

1 MR. HUTCHINSON: Okay. We can take a
2 break.

3 MR. BOWMAN: All right.

4 (Brief recess.)

5 MR. HUTCHINSON: Doctor, we're back on
6 the record. Are you ready to go?

7 THE WITNESS: Yes.

8 BY MR. HUTCHINSON:

9 Q. Is there anything -- have you
10 understood all my questions so far?

11 A. Most of them.

12 Q. Have you -- is there anything about the
13 testimony that you have given that you would like
14 to change?

15 A. No.

16 Q. Doctor, do you have any opinions about
17 how Ethicon's nine products should be changed or
18 modified in the way they are manufactured, and if
19 so, how?

20 A. Specific to manufacturing, no. I don't
21 have any opinions about the manufacturing of the
22 devices.

23 Q. Do you have any opinions about how
24 Ethicon's nine products should be significantly

1 changed?

2 A. Other than what I said before, I
3 believe more testing could have been done to
4 address the question of oxidation, degradation and
5 the clinical implications of that and bench scale
6 testing, preclinical testing could have been done
7 to answer that question. That's also in my report.

8 Q. All right. But outside of more
9 testing -- I want to talk about specifically how
10 you believe Ethicon's nine different products
11 should be significantly changed. Do you have any
12 opinions of how they should be changed?

13 A. How they should be changed?

14 Q. Yes, sir. These nine different
15 products.

16 A. Well, conceptually, they could be made
17 more resistant to in vivo oxidation by looking at
18 the antioxidant package. That could be an
19 improvement. That's consistent with my opinions.

20 Q. And, Doctor, how would you make the
21 mesh in these nine products more resistant to in
22 vivo oxidation?

23 A. I think it needs to be studied. You
24 would have to do testing to identify an antioxidant

1 package that's effective in vivo. I -- I don't
2 know a specific package without doing testing.

3 Q. Doctor, on -- let's talk about the
4 women on Exhibit Number 1 that you're here to
5 testify for.

6 A. Okay. What about the doctors for any
7 of these women? Did any of these doctors commit
8 malpractice by using these Ethicon products in
9 pelvic floor repair?

10 MR. BOWMAN: Object to form.

11 THE WITNESS: I've not expressed any
12 opinion about the conduct of the doctors in
13 implanting these women. I -- I have no opinion
14 about the doctors.

15 BY MR. HUTCHINSON:

16 Q. And, Doctor, do you believe that these
17 doctors who implanted these Ethicon products in
18 these women did anything wrong?

19 MR. BOWMAN: Object to form.

20 THE WITNESS: I've not opined that
21 they've done anything wrong. They implanted the
22 device. I don't know how it was implanted. I
23 don't know when. I haven't reviewed the medical
24 records. So I have no way to assess the conduct of

1 the doctors.

2 MR. HUTCHINSON: And, Doctor, we'll
3 hand you what we'll mark as Exhibit 7 to your
4 deposition.

5 (Whereupon Exhibit 7 was marked as an
6 exhibit.)

7 BY MR. HUTCHINSON:

8 Q. You've seen this study before, haven't
9 you?

10 A. Yes.

11 Q. And this is the seven-year dog study
12 done by Dan Burkley?

13 A. It is.

14 Q. And you've relied on this study in
15 support of your opinions; is that correct?

16 A. Yes.

17 Q. And, Doctor, do you -- if you'll look
18 with me, please, on page 09888221 -- 221 is the
19 last. . .

20 A. 09888221?

21 Q. 221.

22 A. Okay.

23 Q. Down there at the bottom, it states
24 under "Conclusions": "Comparison of 7-year

1 explants to current PROLENE indicate no molecular
2 weigh degradation."

3 Did I read that correctly?

4 A. That's what it says.

5 Q. And, Doctor, do you have an explanation
6 of why the findings in the Ethicon dog study showed
7 no molecular weight degradation?

8 MR. BOWMAN: Object to form. Misstates
9 the document.

10 THE WITNESS: Well, my understanding
11 is, what they did in this study, they sampled the
12 entire volume of the suture and the molecular
13 weight degradation is occurring near the surface,
14 in the outer layers. And so they may have not been
15 able to detect it because mostly what they were
16 testing was bulk polypropylene or PROLENE in the
17 interior of the -- of the fiber.

18 And so in the human explant study, they
19 did see degradation on the surface, but in this
20 study, it was -- it just might have been a sampling
21 problem as to why they couldn't see the loss in
22 molecular weight that I would expect.

23 BY MR. HUTCHINSON:

24 Q. Is that your explanation? It's a

1 sampling problem?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: Well, I'll be more
4 specific. They -- they sampled the whole fiber.
5 Whereas, the molecular weight loss would be
6 expected to occur near the surface of the fiber.
7 And so if the bulk of the fiber had not yet
8 degraded, you wouldn't see it, but you would still
9 see the effects at the surface. You have to sample
10 the polypropylene on the surface as they did in
11 that human explant study. But in this I think it
12 was just the bulk fiber.

13 BY MR. HUTCHINSON:

14 Q. And, Doctor, any time there's a chain
15 scission, there's loss of molecular weight; is that
16 correct?

17 A. Yes.

18 Q. And, Doctor, if you look at the
19 seven-year dog study, other than -- other than a
20 sampling size, do you have any other explanation of
21 why --

22 MR. HUTCHINSON: On page 221, Counsel.

23 BY MR. HUTCHINSON:

24 Q. -- there was a finding of no molecular

1 weight degradation?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: You know, I do have some
4 questions about the controls. You know, this --
5 this control suture is, I don't think, the same as
6 what was implanted.

7 BY MR. HUTCHINSON:

8 Q. It's just not the same size in
9 diameter; is that correct?

10 A. Well, it's -- it's -- it's current
11 PROLENE 40. And so is that what was implanted
12 seven years prior? I -- I don't know the answer to
13 that.

14 Q. Did you make any effort to find out?

15 A. I -- I couldn't tell. I mean --

16 Q. And, Doctor, you'll agree that the
17 control they used was PROLENE, correct?

18 A. It was PROLENE.

19 Q. And, Doctor, if -- what did you notice
20 about mechanical properties of the sutures after
21 seven years of implantation?

22 A. They didn't see changes in the
23 strength, but, again, it's -- it's -- strength is a
24 volume average quantity averaged over the entire

1 volume of the suture, where these changes are
2 occurring at the surface.

3 Q. In fact, Doctor, the physical
4 properties -- or the mechanical properties, rather,
5 of the sutures increased after seven years, didn't
6 they?

7 A. I mean, can you -- what are you looking
8 at? I mean, can you -- I need to look at
9 specific -- to answer that.

10 Q. Did the -- well, did the mechanical
11 properties of the sutures increase after seven
12 years, Doctor?

13 A. I need to look at the -- the data
14 summary again. I need to look -- I need to refresh
15 myself with the data before I answer that.

16 So on page 11336182, there's the
17 seven-year data summary that includes the straight
18 strength, elongation and the modulus.

19 Q. Just focus on my question.

20 A. Well, I'm trying to answer it. I just
21 need to look at the data.

22 Q. You're just kind of reading aloud.
23 Just why don't you look at the data, and then let's
24 focus on my question.

1 A. Okay. I was trying to establish
2 where... so the PROLENE showed -- looks like
3 essentially not -- I mean, it's difficult to say
4 because there's no standard deviations here. So
5 what's significantly different -- I don't -- I
6 don't see standard deviations. But the PROLENE
7 sutures from zero to seven years, the changes in
8 the strength are pretty small.

9 Q. Okay. So, Doctor --

10 MR. HUTCHINSON: So what was my
11 question?

12 THE WITNESS: Well, you said the --

13 MR. HUTCHINSON: No. What's my
14 question?

15 (Whereupon the following question was
16 read back by the reporter: Did the -- well, did
17 the mechanical properties of the sutures increase
18 after seven years, Doctor?)

19 BY MR. HUTCHINSON:

20 Q. That's my question.

21 A. But "mechanical properties" is a broad
22 term. Mechanical properties would include breaking
23 strength, elongation, Young's modulus, that are
24 listed here.

1 Q. Okay. What about toughness? Is that a
2 mechanical property?

3 A. Well, it is, but it's not measured.

4 Q. Okay.

5 A. I mean, what's -- what's reported --

6 Q. So --

7 A. I'm going by what's reported, which is
8 the breaking strength, the elongation and the
9 Young's modulus. The breaking strength, as I said,
10 is staying about the same. The elongation is
11 getting longer and the modulus is going down.

12 Q. Okay. So let's just make sure you and
13 I are on the same page, Doctor.

14 A. Okay.

15 Q. If you can kind of just sit up and look
16 at me.

17 Breaking strength is a mechanical
18 property, correct?

19 A. It's a -- it's a -- it is a mechanical
20 property.

21 Q. Okay. Elongation -- elongation and
22 Young's modulus are also mechanical properties,
23 correct?

24 A. That's right.

1 Q. All right. So if we look at the
2 breaking strength of PROLENE, after seven years, it
3 decreased 5 percent from baseline; is that right?

4 A. That's the percentage that's shown.
5 Right.

6 Q. And elongation increased 111 percent;
7 is that right?

8 A. That's what it says.

9 Q. Any reason to disagree with that,
10 Doctor?

11 A. That's what they measured. I mean,
12 that's. . .

13 Q. In fact, any reason to disagree with
14 any of these numbers on page 183?

15 A. I mean, that's what's reported in the
16 study.

17 Q. Okay. And you --

18 A. So that's what I'm going by.

19 Q. Right. And you have no reason to
20 believe that these numbers are incorrect; is that
21 right?

22 A. Not -- I mean, not incorrectly
23 measured. They --

24 Q. And if we look at Young's modulus, the

1 PROLENE decreased 70 percent; is that correct?

2 A. That's right.

3 Q. All right. And Young's modulus, that's
4 just another word for stiffness; is that right?

5 A. No. Stiffness is a different material
6 property. Modulus is the initial slope
7 approximately of the stress-strain curve. So it's
8 a different property.

9 Q. Right. And -- and, Doctor, what's your
10 explanation for the increase -- mechanical -- or
11 the improvement in the mechanical -- strike that.

12 Doctor, what's your explanation for the
13 improvement of the mechanical properties of the
14 sutures from the seven-year dog study?

15 A. I'm not sure why they're reporting this
16 increase in elongation. I was looking mainly at
17 the comments on degradation, oxidation. I'm not
18 sure why they're reporting this increase in
19 elongation at seven years.

20 Q. Do you have an explanation?

21 A. I just said I don't know why it's
22 increasing at seven years.

23 Q. All right. And, in fact, Doctor, you
24 understood -- we talked about toughness earlier on;

1 is that correct?

2 A. Yes.

3 Q. Do you know if these sutures in the
4 seven-year dog study became tougher after seven
5 years of implantation?

6 A. They didn't report it. I mean, the
7 toughness is the slope under the stress-strain
8 curve, but that's difficult to assess because the
9 elongation is going up, but the stress is -- looks
10 like it's going down. So I -- they didn't report
11 that. So I -- I can't comment on that.

12 Q. Okay. And -- but how would you -- what
13 would you need to be able to comment on toughness?
14 Would you need a stress-strain curve plotting this
15 out?

16 A. That's --

17 MR. BOWMAN: Object to form.

18 THE WITNESS: -- one way to measure the
19 toughness, is the area under the stress-strain
20 curve.

21 BY MR. HUTCHINSON:

22 Q. Okay. And would you need any other
23 data points on your stress-strain curve?

24 A. Other data points on the curve?

1 Q. Yes, sir.

2 A. Well, this is one point, right? So
3 what's -- what you have here is initial slope,
4 which would be the modulus, and then you've got a
5 strength, which would be the -- the -- the endpoint
6 of the test.

7 Q. Okay. So if I understand correctly,
8 what you would need is a stress-strain curve where
9 breaking strength is the y-axis and elongation is
10 the x-axis; is that right?

11 A. No. The y-axis is the stress that's
12 measured, and the x-axis is the strain --

13 Q. Okay.

14 A. -- or the elongation.

15 Q. Okay.

16 A. But it's not a -- what's reported here
17 is the elongation at break, I believe --

18 Q. And --

19 A. -- strength at break.

20 Q. And then what you would also need to
21 look at is the area under the curve at time zero
22 compared to the area under the curve at time -- at
23 after year seven; is that right?

24 A. No. Not really. I mean, it's -- it's

1 a curve. So you can't -- oh -- okay. I think
2 maybe I see what you're saying, look at the whole
3 stress-strain curve measured at zero and then the
4 whole curve measured --

5 Q. Correct.

6 A. -- at seven years.

7 Q. That's correct.

8 A. Yeah, I think that would give you the
9 toughness.

10 Q. Okay. And, in fact, if the area under
11 the curve, after seven years, increased, that would
12 mean the mechanical properties of the suture
13 increased after seven years; is that right?

14 A. No. It would mean that -- the
15 toughness is measured -- approximated by the area
16 under the curve was higher than if the area under
17 the stress-strain curve is higher.

18 Q. Okay. But we can assume that if the
19 area under the curve, after seven years increased,
20 then the sutures used in the dog study became
21 tougher; we can agree to that?

22 MR. BOWMAN: Object to form.

23 THE WITNESS: I don't know. It's a
24 strange finding. It's -- it's very surprising.

1 It's not -- it's -- I -- I have a difficult time --
2 that just doesn't usually happen. It's --

3 BY MR. HUTCHINSON:

4 Q. But -- but my question is can you and I
5 agree that if the area under the curve, after seven
6 years, increased, then toughness of the sutures
7 increased after seven years in the dog study?

8 A. I don't know. I'd have to look at the
9 data without answering that question. I don't -- I
10 need to see -- I need to see those curves and look
11 at it. It just wasn't calculated here. So I don't
12 want to make inferences from their data something
13 that wasn't reported.

14 Q. Okay.

15 A. I mean. . .

16 Q. So you would need to see a
17 stress-strain curve?

18 A. Well, I need to see all the
19 calculations to form an opinion. I'm just going by
20 what was provided. And this is a strange result,
21 that it doesn't do anything for two years and all
22 of a sudden you go to two to seven years, there's
23 this increase in elongation. It's very surprising.
24 You know, I need to see more analysis to make

1 conclusions about toughness and all those things.
2 I mean, I just -- it's not in here, not in this
3 document.

4 MR. HUTCHINSON: Okay. Doctor, I'll
5 hand you what we'll mark as Exhibit 8 to your
6 deposition.

7 (Whereupon Exhibit 8 was marked as an
8 exhibit.)

9 BY MR. HUTCHINSON:

10 Q. This is a stress-strain curve where
11 stress is the y-axis and strain is the x-axis. Do
12 you see that?

13 A. I do. But I have no idea where this
14 came from. It's not in this document, and it's not
15 in this report. And it's --

16 Q. Well, stick with me on my questions for
17 just a second. This shows toughness as -- under --
18 as red at year zero using the same data points in
19 the dog study; is that right?

20 A. I don't know where this came from.
21 This is --

22 Q. I want you to compare it to the dog
23 study.

24 A. You just gave it --

1 Q. And my question is are these the same
2 numbers that are used in the dog study?

3 A. I -- I don't -- I -- this just
4 doesn't -- I don't -- I need to think about this.

5 MR. BOWMAN: Yeah. I'm having trouble,
6 actually, figuring out what you're talking about as
7 well. Is there -- is there somewhere you could
8 point to where this data is taken from?

9 THE WITNESS: I need to see the data in
10 this report. I need to see -- this is break
11 strength versus elongation. I need to see the full
12 stress-strain curve that was measured for these
13 materials. That's how toughness is -- in my
14 understanding, it's the stress-strain curve. This
15 is the break strength versus percent elongation. I
16 need to see the raw data where these -- from the
17 actual test, the stress-strain curve that's used to
18 get the toughness. But I -- I can't comment on
19 this. This is break strength versus elongation
20 which is -- it's a different concept than what I
21 think of in terms of what I've done in my work, in
22 my papers where you plot the stress versus the
23 strain, and you calculate the area under the curve
24 is the toughness. I --

1 BY MR. HUTCHINSON:

2 Q. In fact, Doctor, what we have here is
3 breaking strength on the y-axis, correct?

4 A. This is breaking strength. I'm --

5 Q. All right. And then -- just stick with
6 me and my questions and we'll get through this.

7 We have elongation on the x-axis,
8 correct?

9 A. But elongation at what? Elongation at
10 break? It just says "percent elongation."

11 Q. And then, Doctor, my question to you is
12 are these the same numbers on Exhibit 8 that are in
13 the dog study for breaking strength and elongation?

14 A. I -- I can't answer that question.
15 It's --

16 Q. Well --

17 A. I can't pull numbers off of this graph
18 and say that they're the same from this. I don't
19 know where this came from. I mean, it's not
20 plotted in the right way. It's not plotted as a --
21 as a tensile strength versus strain. It's -- it's
22 not plotted in a way that I'm accustomed -- so it's
23 difficult to infer anything from this sort of
24 analysis.

1 Q. So, Doctor, at year zero, the breaking
2 strength of PROLENE was 1.68, correct?

3 A. Year zero, from the table it says 1.68.

4 Q. Right. And, in fact, Doctor, the
5 elongation at year seven was 1.6, correct?

6 A. Elongation at year seven? No.

7 Q. I'm sorry. The elongation at year --
8 at time zero was 37; is that right?

9 A. That's the number in the table. But is
10 that elongation at break? I assume it is. That's
11 not the stress-strain curve. That's the terminal
12 point of the stress-strain curve.

13 Q. And, Doctor, stay with me. At year
14 seven, elongation is 78 percent; is that right?

15 A. That's what's listed in the table.

16 Q. And the table also lists at year seven
17 breaking strength at 1.6 pounds, correct?

18 A. That's the breaking strength. That's
19 the point at the end of the stress-strain curve and
20 my understanding the way they did this experiment.
21 Right?

22 Q. And the area under the curve at year
23 zero is smaller than the area under the curve at
24 year seven, isn't it?

1 A. I'm not -- I cannot answer that
2 question. This is not -- in order to answer, I --
3 I -- I don't want to be difficult. But in order to
4 answer this toughness question, I need to see raw
5 data. These are -- these are -- these -- these
6 data are plotted at the end of the experiment. I
7 need to see the actual stress-strain curve. I need
8 to know the stress at 1 percent elongation, 5
9 percent elongation, 10 percent, until it breaks.
10 And from that stress-strain curve, you can do more
11 analysis.

12 But this is simply a plot of break
13 strength versus elongation at break. And I -- I
14 can't make those kinds of inferences that you're
15 trying to get me to agree to.

16 Q. Well, Doctor, are you -- have you
17 attempted, in any way, to create a toughness curve
18 to measure the PROLENE sutures from the dog study
19 at year zero and year seven?

20 MR. BOWMAN: Object to form.

21 THE WITNESS: As I said --

22 BY MR. HUTCHINSON,

23 Q. I'm asking you, have you attempted to
24 do that?

1 A. I've not attempted to do it. They
2 report a strength. They report a elongation. They
3 report a modulus. There's this surprising increase
4 from year two to year seven, but --

5 Q. And, Doctor, how would you create a
6 stress-strain curve to evaluate the toughness using
7 the information from the dog study?

8 MR. BOWMAN: Object to form. He just
9 testified that can't be done.

10 THE WITNESS: I can't make it from this
11 table. I would need to see the raw data. Maybe
12 it's in here. I don't know. I haven't -- I don't
13 know.

14 BY MR. HUTCHINSON:

15 Q. But have you looked for the raw data,
16 Doctor, that would support a stress-strain curve
17 analysis?

18 MR. BOWMAN: Object to form. Asked and
19 answered.

20 BY MR. HUTCHINSON:

21 Q. Have you looked for the data, Doctor?

22 A. I haven't looked for those data because
23 it's already shown in the table what I need to
24 know. There's a breaking strength. There's a

1 elongation. There's a modulus. And so I -- I see
2 the elongation and the modulus data at break.

3 Q. In fact, Doctor, can you explain the
4 elongation increase of 111 percent at year seven?
5 Can you explain that?

6 MR. BOWMAN: Object to form. Asked and
7 answered.

8 THE WITNESS: Again, these are volume
9 -averaged tests. You're not looking at the changes
10 at the surface. My testimony has been about these
11 changes that happen at the surface, oxidation. The
12 degradation at the surface is confirmed in this
13 study. This is a volume-averaged mechanical
14 property, and I don't know how to interpret it
15 because it's volume averaged, and they're not
16 looking specifically at what's happening at the
17 surface. That's -- that's the same way I would
18 explain the molecular weight.

19 BY MR. HUTCHINSON:

20 Q. And, Doctor, do you know how to
21 interpret the finding of a decrease of 70 percent of
22 Young's modulus at year seven?

23 MR. BOWMAN: Object to form.

24 THE WITNESS: I'll answer that the way

1 I just answered. It's like molecular weight. It's
2 a -- it's a bulk property measurement, volume
3 averaged across the fiber, and it doesn't tell you
4 about what's happening on the surface. It doesn't
5 tell you whether the surface is embrittled. All
6 it's telling you is about the bulk properties of
7 the fiber. It's the same as the molecular weight.
8 I think limited information can be gained from
9 this.

10 BY MR. HUTCHINSON:

11 Q. Doctor, how -- how can a PROLENE fiber
12 be embrittled if its elongation increases 111
13 percent?

14 A. PROLENE fibers were embrittled in those
15 human explants, and they scraped it off. It was
16 embrittled, oxidized polypropylene. It was in the
17 reports that it was embrittled, oxidized material
18 on the surface. And doing these volume-averaged
19 bulk tests is not going to tell you what's
20 happening at the surface.

21 Q. And, Doctor, does the data from the dog
22 study support your opinions about whether or not
23 PROLENE degrades?

24 A. It says in the report that they were

1 going through -- I believe it says --

2 Q. The data summary. I'm talking about
3 the data summary, Doctor. Stick with me. On page
4 193, the bottom --

5 A. Well, you have to be a little more
6 specific. The mechanical property summary.

7 Q. Excuse me. Excuse me.

8 A. Yeah.

9 Q. Do the mechanical properties, shown on
10 page 183 of the seven-year dog study, support your
11 opinions that PROLENE degrades in vivo?

12 A. I -- I don't think they're relevant to
13 my opinions because they -- this is a
14 volume-averaged quantity, just like the molecular
15 weight. It's averaged over the entire volume of
16 the suture. So it doesn't tell you what's
17 happening at the surface, where the degradation is
18 occurring.

19 Q. Does the data summary support your
20 opinions about degradation in vivo, Doctor?

21 MR. BOWMAN: Object to form. Asked and
22 answered.

23 THE WITNESS: I don't think it can
24 inform my opinions because these are

1 volume-averaged data that don't look at what's
2 happening at the surface.

3 BY MR. HUTCHINSON:

4 Q. Do they support your opinions, Doctor?

5 A. I don't think they inform my opinions
6 because it's a volume-averaged property. It
7 doesn't look at what's happening at the surface.

8 Q. You don't --

9 MR. HUTCHINSON: Move to strike as
10 nonresponsive.

11 BY MR. HUTCHINSON:

12 Q. You don't think they inform your
13 opinions. My question, Doctor, is do the -- do the
14 data summary support -- not inform -- support your
15 opinions that degradation occurs in vivo with
16 PROLENE? Does this data support -- does this data
17 summary support your opinions?

18 A. Again, it doesn't -- I -- I don't know
19 what to do with these data. These are
20 volume-averaged properties. It doesn't tell you
21 what's happening at the surface.

22 Q. I'm not asking you what -- to do
23 anything with them. I'm asking you whether or not
24 this data summary supports your opinions that

1 PROLENE degrades in vivo?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: It's --

4 MR. BOWMAN: Asked and answered.

5 THE WITNESS: It's difficult to form an
6 opinion about it because they're not measuring the
7 right thing. They're measuring a volume-averaged
8 property, not what's happening at the surface. So
9 it's difficult to form an opinion.

10 MR. HUTCHINSON: Move to strike as
11 nonresponsive.

12 BY MR. HUTCHINSON:

13 Q. Doctor, does the data summary support
14 your opinions?

15 MR. BOWMAN: I'm instructing you not to
16 answer.

17 THE WITNESS: I'm not answering. I
18 don't -- I don't want to go back and forth anymore.
19 I believe I've answered it.

20 BY MR. HUTCHINSON:

21 Q. Doctor, I forgot to ask you one
22 question when we were talking about the nine
23 different products. Can you tell the jury what the
24 difference is between TVT EXACT and TVT and any

1 other -- and in any of the other TVT products?

2 MR. BOWMAN: Object to form.

3 THE WITNESS: I don't remember the

4 specific differences. There's differences in how

5 the mesh can be cut, machine cut, laser cut.

6 They're all made from the same mesh, which is what

7 I was looking at in my report. They're all made

8 from the same PROLENE, from the same -- from the

9 same mesh, as I said earlier.

10 BY MR. HUTCHINSON:

11 Q. Doctor, is TVT ABBREVO laser cut or

12 mechanically cut?

13 MR. BOWMAN: Object to form.

14 THE WITNESS: I can't remember. I

15 believe it's laser cut. TVT's mechanically cut. I

16 don't remember the details of it.

17 BY MR. HUTCHINSON:

18 Q. Doctor, do you know -- can you tell the

19 jury whether or not TVT-O is mechanically cut or

20 laser cut?

21 A. I believe TVT-O is mechanically cut.

22 Q. Doctor, are you aware of whether or not

23 TVT-O is available in any type of other -- strike

24 that.

1 Are you aware if TVT -- if TVT-O is
2 available in laser cut mesh?

3 A. I can't remember. Some of these
4 products are offered as machine cut and laser cut.
5 It's not always specified which the cut is.
6 Sometimes it's difficult to figure out. But --

7 Q. Is it your testimony, Doctor, it's not
8 always specified in the product literature how the
9 mesh is cut?

10 A. I don't remember how the -- how the --
11 the specifics of how the mesh is cut. Again, I was
12 focusing on the specific PROLENE used in the mesh
13 and its implantation in the body.

14 Q. Doctor, can you tell us how the mesh in
15 the TVT SECUR is cut?

16 A. I believe that's a machine cut.

17 Q. And can you tell us, Doctor, how the
18 mesh in TVT EXACT is cut?

19 MR. BOWMAN: Object to form.

20 THE WITNESS: I don't remember about
21 TVT EXACT.

22 BY MR. HUTCHINSON:

23 Q. Can you tell us how the mesh in PROSIMA
24 is cut?

1 A. PROSIMA is not a sling. It's a --

2 Q. I'm not asking about the product. I'm
3 asking about can you tell us how the mesh in
4 PROSIMA is cut?

5 A. I -- I don't remember. I wasn't
6 stating opinions about the cutting of the mesh in
7 my report.

8 Q. Doctor, does the cutting of the mesh
9 influence your opinions whatsoever regarding
10 oxidizing PROLENE?

11 MR. BOWMAN: Object to form.

12 THE WITNESS: Well, the cutting of the
13 mesh could affect the oxidation reaction.

14 BY MR. HUTCHINSON:

15 Q. Is that stated in your report marked as
16 Exhibit 2, Doctor?

17 A. I don't believe that's in my report.

18 Q. Okay. Doctor, can you tell us how the
19 mesh in GYNEMESH PS is cut?

20 MR. BOWMAN: Object to form.

21 THE WITNESS: I don't remember how that
22 mesh is cut.

23 BY MR. HUTCHINSON:

24 Q. Can you tell us how the mesh in PROLIFT

1 is cut?

2 A. I don't remember how that mesh is cut.

3 Q. Can you tell us how the mesh in
4 PROLIFT+M is cut?

5 A. I don't remember how that mesh is cut
6 either.

7 Q. Doctor, do you have any opinions
8 whatsoever regarding how the mesh is cut as it
9 relates to its reaction with tissue?

10 MR. BOWMAN: Object to form.

11 THE WITNESS: I mean, I thought I
12 answered it. Those opinions are not in this
13 report.

14 BY MR. HUTCHINSON:

15 Q. And you're not offering any opinions
16 about that in relation to the nine different
17 products at issue here today, correct?

18 A. I'm not offering any opinions about
19 that.

20 Q. Doctor, have --

21 MR. BOWMAN: Counsel, I actually have
22 that the three hours are up.

23 MR. HUTCHINSON: Okay.

24 BY MR. HUTCHINSON:

1 Q. Doctor, do you intend to offer any
2 opinions in this case that we've not already
3 discussed?

4 A. No.

5 Q. Do you plan on supplementing your
6 opinions?

7 A. I don't know.

8 Q. Okay. Have you understood all of my
9 questions so far?

10 A. Mostly.

11 Q. Is there a question that's lingering in
12 your mind that you don't understand that I need to
13 reask?

14 MR. BOWMAN: I did instruct him not to
15 answer at least two questions.

16 THE WITNESS: No.

17 BY MR. HUTCHINSON:

18 Q. Doctor, is there anything about the
19 testimony you've given today that you would like to
20 change?

21 A. No.

22 Q. Do you feel good about how you did
23 today as an expert witness?

24 MR. BOWMAN: Object to form.

1 THE WITNESS: I don't know. Our three
2 hours is up. I think we're done.

3 MR. HUTCHINSON: Thank you.

4 Counsel, before we go -- we go off the
5 record, just to make a housekeeping note, counsel
6 has given me a flash drive that contains what?

7 MR. BOWMAN: Reliance materials, pretty
8 much everything that was reviewed or referenced in
9 the report.

10 MR. HUTCHINSON: Okay.

11 (Proceedings concluded at 12:17 p.m.)

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1 C E R T I F I C A T E

2 STATE OF TENNESSEE)

COUNTY OF DAVIDSON)

3 I, Lise S. Matthews, RMR, CRR, CCP, LCR
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